IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

THE CITY OF HUNTINGTON,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01362
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	
CABELL COUNTY COMMISSION,	:	Civil Action
Plaintiff,	:	No. 3:17-cv-01665
v.	:	
AMERISOURCEBERGEN DRUG CORPORATION, et al.,	:	
Defendants.	:	

BENCH TRIAL - VOLUME 2
BEFORE THE HONORABLE DAVID A. FABER, SENIOR STATUS JUDGE
UNITED STATES DISTRICT COURT
IN CHARLESTON, WEST VIRGINIA

MAY 4, 2021

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PROCEEDINGS had before The Honorable David A. Faber, Senior Status Judge, United States District Court, Southern District of West Virginia, in Charleston, West Virginia, on May 4, 2021, at 9:00 a.m., as follows:

THE COURT: Good morning, everybody.

SIMULTANEOUS SPEAKERS: Good morning, Your Honor.

THE COURT: I want to put a couple of things on the record before we get rolling here.

The second motion to exclude the expert testimony of Dr. Gupta is before the Court and I'm going to deny the motion at this time and allow him to testify on all the disputed points conditionally admitting the testimony. That will give me an opportunity to make a -- to consider the issues in a more complete context and, after hearing the testimony, I'll decide what parts, if any, should be excluded.

Also, there are currently pending two motions regarding deposition testimony that the plaintiffs intend to offer. That's Nathan Hartle and Thomas Prevoznik. I understand that the plaintiffs object to the filing of these motions because they contend it violates the order establishing procedure for designation and use of deposition testimony at trial, as well as the deadline for filing motions in limine.

Because this is a bench trial and I have more discretion and flexibility in ruling on evidentiary

objections, my plan to handle these types of motions is to defer ruling on them and to consider the motions, along with the specific deposition designations and the objections thereto. Therefore, I want to make clear that, in general, I'll consider any motion that is filed, but do not expect a ruling before the deposition is offered. If a motion is filed that I believe requires an immediate ruling, I'll let the parties know an accelerated timeline for responses and the replies thereto will be set.

Otherwise, the deposition or the portions thereof offered will be considered by the Court subject to later rulings on the objections. The bench trial format makes it appropriate for the Court to do this because there's no danger to misleading or confusing a jury.

I hope that gives us some guidance that will help move the trial along. I realize that decision might lengthen things a little bit, but I think that's, in my opinion, the best way to handle it.

All right. If the plaintiffs are ready, you may present your first witness.

Yes, ma'am?

MS. MAINIGI: Your Honor, two preliminary things that I wanted to raise with the defendants. One, Your Honor, I wanted to confirm that an objection by one defendant would apply to all defendants so that we're not

all objecting at the same time. I think Mr. Farrell has no problem with that.

THE COURT: Is that what all the defendants want?

MR. SCHMIDT: Your Honor, subject to, if we have our own objections, being able to make them.

COURT REPORTER: Could you ask them to state their name each time for me?

MS. MAINIGI: I'm sorry. Enu Mainigi for Cardinal Health. Sorry.

MR. SCHMIDT: I apologize. Paul Schmidt for McKesson.

MR. NICHOLAS: Bob Nicholas for AmerisourceBergen and that procedure is fine with us.

THE COURT: All right. That will be the rule. An objection by one defendant applies to all unless a defendant opts out.

MS. MAINIGI: There may be from time to time a specific objection related just to Cardinal or just to McKesson, Your Honor, in which case, someone else may pop in.

The other issue is, Your Honor, could we have a standing objection related to some of the evidence that relates to our summary judgment motions? So, for example, a standing objection to the admission of evidence prior to January, 2016 for Huntington and prior to March, 2016 for

Cabell based on statute of limitations grounds. Obviously, we don't want to lodge objections as the evidence is coming in, so I thought if we could have a standing objection, that takes care of everything.

THE COURT: Does anybody have a problem with that or an objection to that?

MR. MAJESTRO: No, Your Honor.

THE COURT: All right. That's fine. That's what we'll do. And I appreciate you pointing that out. Otherwise, we'd have to deal with objection after objection.

MS. MAINIGI: Yes, Your Honor. Thank you, Your Honor.

THE COURT: All right. We're ready to start the evidence. You may proceed.

MR. FARRELL: Paul Farrell, Jr. First, Judge, I wanted to take just a second and introduce to you two of my colleagues that are here today that were not here yesterday --

THE COURT: All right.

MR. FARRELL: -- because of the crowded courtroom, Mr. Troy Rafferty and this is Erin Dickinson.

MS. DICKINSON: Hi, Your Honor.

MR. FARRELL: The plaintiffs call Dr. Corey Waller.

THE COURT: And you're noting their appearances

for the trial, is that --

MR. FARRELL: Yes.

THE COURT: Okay. All right. Dr. Waller.

COURTROOM DEPUTY CLERK: Would you please state your full name?

THE WITNESS: Dr. Robert Corey Waller.

THE COURT: Would you spell your last name, please?

THE WITNESS: W-a-l-l-e-r.

COURTROOM DEPUTY CLERK: Thank you.

Please raise your right hand.

DR. ROBERT COREY WALLER, PLAINTIFF WITNESS, SWORN

COURTROOM DEPUTY CLERK: Thank you. Please take a seat.

DIRECT EXAMINATION

BY MR. FARRELL:

Q. Good morning, Dr. Waller.

A. Good morning.

Q. Will you please introduce yourself to the Court?

A. Good morning. I'm Dr. Robert Corey Waller.

Q. And what is your profession?

A. I am an emergency medicine, addiction medicine and pain medicine physician.

Q. What is your understanding of why you've been asked to come here today?

A. From a 30,000 foot view, it's to discuss concepts of opioids and addiction.

Q. All right. And have you ever served in the capacity of having these discussions with the Court before?

A. From an educational standpoint and not in a testimony standpoint, I've educated the Judiciary of the State of Michigan and Idaho on these things recently.

Q. Okay. Can you explain a little bit more? What does that mean?

A. Well, I was asked to present on addiction and how it really intersects with the behaviors seen from those being adjudicated upon and how substance use disorders, you know, impact decision making and a number of the things that affect the way in which they're adjudicated.

Q. Other than -- other than -- let's talk about the education. You said you were in a teaching capacity for this in the State of Michigan. Describe that.

A. I am an associate professor at Michigan State University. I have been for a number of years. However, I teach all over the country, not just in a single location, as a part of technical assistance and training for team-based approaches to care from everything from pain building out multidisciplinary pain clinics to teaching and training entire states worth of personnel around addiction treatment and all of the accompanying issues.

Q. Who are you teaching?

A. Physicians, PAs, nurse practitioners, nurses, social workers, really, the entirety of the team that it takes to treat a patient with addiction.

Q. And the second thing you said is something -- was it Iowa? Idaho?

A. Idaho.

Q. In what teaching capacity were you in Idaho?

A. I was asked to give a -- a didactic lecture with question and answer session; specifically, about really the neuroscience of addiction and how that impacts the behavior that they see in a number of the people in their courts.

Q. And so who was it that invited you to give that lecture?

A. It was the Chief Justice. I don't recall her name at this point in time.

Q. Of Idaho? So it was the Judiciary?

A. Yes.

Q. Have you ever given sworn testimony before a legislative body?

A. Yes. I've testified to Congress, U. S. Congress, and the House specifically.

Q. On what topic?

A. On addiction and, specifically in that instance, it was the utilization of medication-assisted treatment for opioid

use disorder.

Q. So, aside from your -- your teaching capacity and your Congressional testimony, the two topics, opioids and addiction, what qualifies you to offer opinions in this case on those two areas?

A. Well, for opioids, you know, I have a pretty deep background starting with my undergraduate degree, graduate degree, and then medical school around not only the synthetic chemistry associated with those and the molecular biology and how they act, but also, the clinical implications and use of those drugs in humans and in populations.

And then for addiction, I am board certified in addiction medicine and have been for well over a decade, and really have built out entire pages of guidelines and books surrounding this for a number of years.

Q. All right. So, let's start with the basics. Please tell the Court what your educational background is.

A. I have a Bachelor's of Science in Biology. I have a Master's of Science in Biology, with a neuromolecular focus. I have a medical doctor degree.

Q. All right. And what about your training? What training have you had in these two specific areas?

A. As an emergency -- my residency was in emergency medicine and, in that, you get a deep training in toxicology

and the really physiological effects of drugs and a number of other intoxicants.

And then, afterwards, I went through what they call the practice pathway for addiction medicine and pain medicine where you spend 2,000 hours specifically working in that field of study with mentors and oversight.

For addiction medicine, I sat for the Boards because it was very pertinent to the work I was doing. For pain medicine, I decided since I was already the medical staff Chief of Pain Medicine for a large health system and doing the work I was, it didn't make sense to go through that pathway.

Q. So, aside from your training, have you held any positions or leadership positions within healthcare institutions?

A. Yes. Specifically, at Spectrum Health, I was the -- elected the Medical Staff Chief of Pain Medicine and it's a $3 billion dollar healthcare system with twelve hospitals and about a thousand employed docs and the Department of Anesthesia elected me to run that division.

Q. Are you a member of any professional organizations?

A. Currently, the AMA and the American Society of Addiction Medicine. I spend most of my time with the American Society of Addiction Medicine.

Q. Are you published?

A. Yes.

Q. Describe your publications.

A. There's been a string of them. I think, to bucket them, there's the basic science publications, you know, that were included as a portion of my thesis for graduate work around neuroscience; specifically, around the areas of brain cancer and subcellular pharmacokinetics of synthetic drugs that we developed.

And then, past that, next was publications surrounding the identification of kind of the causal relationship for utilization in the healthcare system for high frequency utilizers to Emergency Departments, and then it moved into more of the translation of research into writing of chapters and books. And I'm currently the Editor in Chief of the ASAM criteria, which is the nationally accepted book for how someone is determined to be what level of care and what treatment type they should be getting for addiction and was one of the co-editors on a pain and addiction book, as well.

Q. You said an acronym. You said ACM?

A. A-S-A-M, ASAM, American Society of Addiction Medicine.

Q. And what is that organization?

A. It's a national professional organization that has -- it's not only physicians, but also licensed personnel that treat patients with addiction and their focus is really to bring together the people within that profession to develop

guidelines and pathways. And they are the sponsor and have been for the last 35 years of the ACM criteria that is utilized nationally.

Q. Yesterday, in opening, I told the judge that I was going to ask you to come and talk about the morphine molecule in the brain. Before we get there, I'm going to put you on the spot.

A. I feel on the spot.

Q. Fair. Between the morphine molecule and the brain, I'd like you to tell the judge why you think, for those two topics, what's the most impressive credential that you have that you can tell the judge so that he thinks, yeah, this guy is qualified.

A. Well, I think for the morphine side of it, I think it's a couple of pieces, but one specific one for the morphine is the research that I did in graduate school which really focused on the synthetic development of molecules that are utilized in the brain and then having to identify very specifically where they impact the brain, where they're located in that brain, and then applying that into clinical research. That was on top of years of teaching Organic Chemistry and Biochemistry through undergrad and graduate school.

I think for the brain piece, I really, from that, have spent a number of years really trying to deeply understand

behavior and why those -- what in the brain spawns certain behaviors or locks in certain behaviors and how they're really interconnected in a way that becomes predictable given especially since addiction is based on behavior and not -- not a lab test.

Q. Aside from the academic side of what you've done, have you also treated people?

A. I have. I've treated people for years both in the capacity of emergency medicine, but then I had a specific clinic in Grand Rapids, Michigan that we opened dedicated to those people in the ER ten or more times per year and, in that, we had a very high density of people with really complex combinations of pain and addiction.

Centers -- CMS, Centers for Medicaid and Medicare Services, designated us as the protoype for what they call ambulatory ICU because we have developed a fully integrated method to really identify and stabilize these patients.

And then, after that, I -- I did that for a number of years and then went and did street medicine in Camden, New Jersey where I was having to identify really a very complex group of patients, sometimes various -- under bridges and in the streets trying to understand how this acts inside of a community.

Q. So, what is street medicine?

A. Well, that's -- pragmatically, that's exactly what it

sounds like. You kind of sling on a backpack and wander and try to find those patients that have been lost to the system and, once you identify them, you treat them where they are, in the street, under a bridge, somebody's house.

Q. All right. So, in general, do you consider yourself an expert or hold yourself out as an expert in certain fields of medicine? And I'll give you a hint. We've prepared a slide on it.

A. I do, yes.

Q. Okay. What fields are those?

A. Well, I would say neuroscience particularly and, more specifically, around the neuroscience of behavior and addiction, and then addiction as a whole, both from the theoretical and neurobiological sense, but also, the clinical application of treatments and interventions for addiction.

And then for pain, really specifically the intersection between pain and addiction and the treatment of those individuals who either have both or have high risk/high dose medications that need to be modulated.

Q. Thank you.

MR. FARRELL: Judge, at this time, I will tender Dr. Corey Waller as an expert in the fields of neuroscience, addiction and pain.

THE COURT: Any objection?

MS. WICHT: No objection, Your Honor.

MR. NICHOLAS: No objection, Your Honor.

THE COURT: All right. I find Dr. Corey Waller to be a qualified expert in the fields of neuroscience, addiction and pain.

BY MR. FARRELL:

Q. First chapter down.

A. Okay.

Q. Let's start with our discussion. Let's start right there. Can you describe to the Court, tell the Court what are opioids?

A. Well, so opioids are a class of molecules, so a combination of elements and chemicals that have a particular function and that function is that they enter the body, they bind to a receptor, an opioid receptor. The one really that I'll talk more about today is what we call a mu opioid receptor, the one that has most of the activity from the opioids.

But it also includes, you know, naturally occurring peptides, the things we make for the natural system of pain treatment called like endorphins and enkephalins and these things that help us in our own pain treatment without any outside input.

Q. Doctor, let's stop for a second. You talked about the body's natural endorphins and I'd like to delve into the

body's natural production first.

MR. FARRELL: Judge, if it's okay with you, may the witness step down and play with our interactive screen?

THE COURT: Yes.

THE WITNESS: Is it okay if my mask stays off when I go down?

THE COURT: Yes, absolutely.

MR. FARRELL: Judge, we understand that in my ambulation yesterday away from the phone, I had forgotten to turn on my lapel mic. And so, I was just making sure he had a sound check on his lapel mic.

All right, Doc --

THE WITNESS: Testing. Everybody hear me okay? Projection is rarely an issue.

So, I think I'm going to start with the simplest --

MS. WICHT: Your Honor?

THE WITNESS: Kind of version of this.

MS. WICHT: Your Honor, I apologize. I assume we're still going to proceed by question and answer, right? I just didn't hear a question.

THE WITNESS: Oh, I'm sorry.

THE COURT: Yes. I will sustain the objection, if there was one.

MR. FARRELL: Okay.

BY MR. FARRELL:

Q. So, Doctor, what's this?

A. So, this is a simplistic representation of what we would call a synapse and, more importantly, this is the way in which all of the nervous system really communicates. So, signal is sent from this axon and it lands on the next one. And the way that it communicates its signal is two-fold. And that has to do with whichever chemical is released and whichever receptor that it binds to.

So, naturally, if I needed to treat pain or stabilize mood in the body, I would release endorphin or enkephalin. That would then come down and bind specifically to this receptor. And, in this particular case, we're talking about the mu opioid receptor, which is a receptor that binds to an opioid or a naturally occurring peptide like endorphin or enkephalin or dynorphin and when that binds to it, it sends a signal down here, which produces an action, and that action may very well be a decrease in pain, a stabilization of mood, a decrease in breathing, or the opposite of that, if we decrease the amount of this.

Q. Doctor, I'm going to interrupt you real quick because you used a bunch of big words. So, the first thing I want to ask you is this. What is the drawing on there? It looks like a knee joint. What is this?

A. Well, this is --

Q. Describe it for the Court.

A. Yeah. This is a synapse. And so, this is the connection between one nerve connecting to another. And so, if you think about it in the brain, there are a number of these in the brain, billions of these connections in the brain, and these interact in a way to send a signal. And it's not -- it's not unlike the kind of equivalent of the internet going to the house and then having to be connected to a box that turns it into Wi-Fi and then sends that signal down. And so, that's, you know, one of the ways that you can think is that this is a message getting in. It has to be translated to this other part of the brain. It's translated when a chemical binds to a receptor and sends that signal.

Q. All right. And so, what are the little yellow balls?

A. Those, in this case, would be what we would call a neurotransmitter. It is a general term. Now, we'll be talking about opioids in the form -- if I take a pill, then they wouldn't come necessarily from here. They would just enter into this synapse and bind to this.

If it's naturally produced, it will come through the synapse and be released when the body feels like that it needs it.

Q. Now, the receptors that you pointed to and you called it mu, what's a mu receptor?

A. The mu is just the Greek designation for the receptor

and we have, you know, all the way through, you know -- now we have it all the way through -- I guess, 18 of them. Sorry. I don't speak Greek.

So, at the end, but as we go out, there are 18 different receptors and they were basically named as they were found and they just gave them the Greek designation as they went up.

Q. So, are there different kinds of neurotransmitters?

A. Well, of course, and this is how the body really creates subtle reactions rather than just having everything happen at once. And so, you can release a combination of neurotransmitters even into this and have it bind to a mu receptor or maybe a -- you know, so, at the end, this is where the body starts to fine tune a response rather than just having this goes to here and does only A. It can do A, B, and a little bit of B and some C from that and it allows for all of those neurotransmitters to work.

Q. How many types of neurotransmitters are there?

A. There are hundreds that we know of and there are a few big ones that you've probably heard of, as well. So --

Q. So, we're not going to go through the hundreds of them.

A. No, no.

Q. Let's talk about the ones that are germane to your particular expertise in the opium and the neuroscience addiction. What are the particular neurotransmitters that

are applicable to this issue?

A. Well, I think the natural neurotransmitters, you know, which could be called hormones, you know. And so, you have endorphins and enkephalin and dynorphin. Those are the three that are the major ones that help us to modulate, in this case, pain, and mood, and a number of other things.

But, in general, you have endorphins. So, this is the main player when it comes to natural pain management. It also helps to stabilize mood. It's the one that's responsible for a runner's high. Like, if you go out and go for probably too far of a run and you feel like this is great and then, an hour later, not so much.

But then, enkephalins, is -- it does a little bit of that. It overlaps. But this helps more with mood and then dynorphins will also help with pain by binding to that receptor, but can also act as a little bit of a stopping point for endorphins and help to modulate it in the middle.

Q. Doctor, let's spend a minute and let's talk about the molecular structure of each of these.

A. I think I had a slide for kind of the --

Q. We're having -- there we go. So, before we start, explain what a molecular structure is as -- as if I don't have any idea what the molecular structure means.

A. So, a molecular structure is where I would take a number of elements, so that would be carbon, or nitrogen and

oxygen and, you know, and we start to put those together. And when those come together, they come together into a molecule. And so, the structure of that molecule would be the molecular structure. And some molecular structures are very simple, some are very complex.

In the case of these, these are naturally produced. They come from the DNA. They get translated into what we call peptides. And then, these peptides, you know, ultimately can be modified in a bunch of different ways.

So, this is complex just in its basic form with endorphin, but the body can even modify it more and it can decide it wants to add a hydroxyl group, which is an -- you know, an oxygen and a hydrogen. It can add a methyl group, which is carbon and hydrogen. It can do all of these things.

And when that happens, the important piece is that it changes the formation. So, when it -- when it adds something of distinction in a specific location, you can actually change how it works and how it really applies that action to the receptor.

Maybe it only binds it a little bit now. Maybe it binds it more, depending on what the body needs. Each of these can be modified in that way so that it really creates a pathway of kind of infinite modification of the body's response to a given pain or a given stimulus.

Q. So, why is this important?

A. Well, this is important because we, as humans, interact with a bunch of, you know, different things in the world.

You know, my -- my dad was a Marine and he used to tell me the story about when he got, you know, shot and just finished the mission and went on. He didn't really think about it.

Well, that's because he had a really good -- well working endorphin system and he had, you know, dynorphin that was helping to suppress mood and he was able to kind of push through that and not even think about it and do what he had to do.

A mother giving birth. You know, I've delivered a baby on a road in Honduras in -- after a hurricane. And she was exquisite. It was amazing. Like she just went through it like it was nothing and that was endorphin and enkephalin and dynorphin really working in its natural form. And it did all that without making her stop breathing. It did all that without getting her intoxicated. It just treated the pain and allowed her to do all of those pieces.

And so, this is why the system is so interesting and unique, and why I've spent so much time trying to understand it because it's subtle in what it does. It's not -- it's not a hammer. I mean, it just -- it can tweak it just enough to get you through what you need to get through.

Q. What about the other -- you talked about the endorphin molecular structure. Can you talk briefly about the other two?

A. Sure. So, enkephalin is a little more simplified. Also has a simpler job. Its job is to really stabilize a couple of parts of the brain and mostly that has to do with the way we react to pain. So, enkephalin can be tweaked to either stabilize a mood while you have this pain so that you're not freaking out in the middle of a pain symptom or it can under-do it so that it's fight or flight and so, you have pain. You need to get out of here. It's okay to freak out. And so, that's really what this one does.

And then, dynorphin still works a little bit on mood, but helps to manage how we feel pain and a sense of do we feel it as heaviness, do we feel it as burning, do we feel it as that. And these coupled with a multitude of other molecules, substance -- I mean, there's just so many that actually work together to create this really ultimately symphony of things.

And I guess, you know, the analogy that I've used, you know, with you and everybody is really that this is the equivalent to a sound board. And, in a sense, like if you're in a studio and you have a hundred different mics and fifty different instruments and you're going to record something, you can tweak each of these sounds to get just

the perfect sound from that.

And this is really the natural system. And the natural system, as we turn these knobs, allows us to react to -- with subtlety -- to everything around us.

You know, I have a torn rotator cuff. And so, just putting the jacket on sometimes is requiring a twisting of these knobs to do that. But when that happens, it's over and you move on, and you go through, and you don't have a leftover feeling or some other side effect.

Q. So, Doctor, so jumping ahead, when we get to the manmade response, what's the difference between the body's reaction when you have the natural or the synthetic version of these chemicals?

A. Well, if we talk about opioids that are exogenous, meaning given from the outside, they're super simple in their formation. And so, they kind of have one thing that they do. They're not capable of subtlety. So, instead of this multitude of symphonic changes that we can make on a sound board, it's -- it's a volume knob. It just -- that's it. It's either on and way up, or on and a little less up. So, it's really just dose dependent and then it just rotates this up or down. And that's it. There's no subtlety to it.

And where I talk about from the natural system you can have an endorphin that works just in one small part of the brain but doesn't go anywhere else, isn't released in your

brain stem, isn't released at the same time in your belly, you now have, you know, exogenous medication. When it comes to here, it hits every one of the mu receptors. Not just the ones that needed to be hit. And so, it's hitting the ones in the belly. It's hitting the ones in the brain stem. And so, it gets overwhelmed.

And then, as you turn it up, what it does is, it just does more of that same. And then, in the case of what we find with these, that's -- that doesn't work well long-term.

Q. Doctor, let's talk about the --

MR. FARRELL: And, Judge, if you would want to jump in and ask any questions, I would be happy to turn the mic over.

THE COURT: You're doing fine, Mr. Farrell, as far as I know.

(Laughter)

MR. FARRELL: Not necessarily a ringing endorsement, Your Honor.

THE COURT: That's the first time I've ever had a lawyer in thirty years on the bench invite me to intervene in his direct examination.

MR. FARRELL: Well, to be fair, Your Honor, I've read a few of your transcripts. Usually, the lawyer doesn't need to ask permission.

BY MR. FARRELL:

Q. All right. So, Doctor, we're talking about exogenous opioids, right?

A. Correct.

Q. Let's talk about a couple of different categories of them.

A. Sure. So, the, quote, "exogenous opioids", the ones that we would take and put into the body come really in three major forms. And one of those is the natural opiates which come from the poppy plant. And those are, you know, morphine, codeine, thebaine. There are a bunch of other chemicals inside of opium, you know, that can be extracted, but these are the ones that are really chemically active and thought about.

And then we have the semisynthetic opioids and these are the ones that start naturally, but they go to a lab and get modified. And these are the ones that we're more familiar with that we see in, you know, heroin, oxycodone and hydrocodone.

And then, fully synthetic, and those are the things that start and finish in a lab. And one of those would be Fentanyl. And each of these have a laundry list of other things that are there but, ultimately, the ones that we see the most are going to be things like morphine, codeine and then the three that are in the semisynthetic opioids.

Q. All right. So, I'm going to ask a couple of simple

questions again. So, when we're talking about the first category of opiates --

A. Yeah.

Q. You said these are naturally occurring chemicals or naturally occurring derivatives. Explain what that means.

A. So, these are produced inside of the poppy plant, and naturally, so these live in there. And they're pretty small amounts, you know, in each plant itself. So, if you just went and grabbed a poppy plant and you ate it, you're really not going to get anything from that except probably nauseous.

But when did -- when we found out that you could, you know, really extract these and condense what's in there, that's what became opium. So, opium is not a thing. It's a combination of things.

Another way to think about is like marijuana has a bunch of things in it. It's not just one thing. This is -- opium is the same.

So, when somebody smokes opium, they're getting a combination of these and it's hard to tell how much of which because it's a plant derived and so, we're not sure.

Now, with the plant, we've now figured out, you know, a long time ago how to industrialize this and pull this stuff out in a higher concentration.

Q. All right. So, once we pull out -- or once we get the

poppy, how do we get the stuff from the poppy plant, the juice, and how do we -- how do people turn it into morphine, codeine and thebaine? How do they separate it out?

A. Well so, these can be, you know, separated based on a combination of their molecular weights and the -- we -- you know, we call it kind of the electron charge that they have. So, they can be -- they can be separated through pretty standard industrial means that we would separate combinations of meds, of drugs or molecules.

And once those are separated, then they can be purified even further through other means. You know, what we would you know, column separation. And there are a bunch of different ways to do it.

And for morphine, there's probably seven different ways that are industrialized in how to identify and pull that out and more even for codeine. Thebaine, interestingly, while we don't hear much about that, is the starting point for, you know, oxycodone and in there. So, it by itself doesn't do much.

So, this one, if you take it, just makes you nauseous and doesn't really do anything. Codeine, as we say, is an opioid in the true sense where it binds to that receptor, but it also has a lot of side effects. So, it has kind of a block, a ceiling effect because you take enough and you're nauseous and throwing up with codeine.

Morphine is a little different in that it's what we would call a clean binder of the receptor. It doesn't have a lot of other things that it does because it just goes in and binds.

Q. So, the second category is semisynthetic opioids. So, I want to start with -- first, we've changed the word opiate to opioid.

A. Right. So, opioid is the term that kind of encapsulates, again, as I stated earlier, all of those molecules that will bind to an opioid receptor and cause an effect.

And, again, there's a bunch of different opioid receptors. The one we focus on, because it's the one most correlated with either bad outcome and pain relief is going to be the mu opioid receptor. So, heroin, oxycodone and hydrocodone all bind to that, but because it's not a true opiate, meaning that it's there, it's now semisynthetic.

So, an opiate is an opioid. A semisynthetic -- and so, you'll actually find some discordance in books in this where you'll see this called a semisynthetic opiate because it's directly derived from this. So, this term here can go both ways. It doesn't matter.

Opioid is the umbrella. Opiate is specifically deprived molecules from opium or its closely developed cousins.

Q. Now, the other word in the middle, synthetic what does that mean?

A. That means I have synthesized a new version of a molecule. So, if I have morphine and I added an oxygen, I have now synthesized it. If I have morphine and I added a carbon group, I've now synthesized a new molecule. So, synthesis is a general chemical term for made or changed.

Q. So, how would you make or change a molecule?

A. Well, I mean in a lab, you can put it in. And so, the simplest one is, you know, you can take acidic acid and morphine and create a version of a very -- I guess the easiest thing is you can add that and create a version of heroin because you've acetated, you know, morphine.

So, it's diacetylmorphine, is what heroin is. And so, as we look at these chemicals, you recognize it's many times one or two steps to get to here, which is why this is so cheaply made from a number of places.

And then these just --

Q. Hold on. Hold on real quick because I need to get some spellings down.

A. Okay.

Q. You said that heroin is basically diacetylmorphine?

A. Well, heroin is diacetylmorphine.

Q. I see.

A. I mean, that's the actual chemical name for it.

Q. Can you spell that?

A. No. D-i-a-c-e-t-y-l-m-o-r-p-h-i-n-e.

Q. Perfect.

A. Now it's on the record and I'm probably going to get spellchecked on that.

Q. That's all right.

A. I can make it. I can't spell it.

Q. The first word, it says semi. Why do you -- why do we put that qualifier in there, that it's not a synthetic opioid, it's a semisynthetic opioid?

A. Well, semisynthetic means that we started with the natural origin. So, we started with the natural product in which we just added to, rather than starting from scratch, which is what fully synthetic would mean.

Q. Perfect transition. Synthetic opioids, what's the key distinction between semisynthetic opioids and synthetic opioids?

A. Well, synthetic opioids, again, are we've identified what we want to do. We look at a receptor and we say what shape do I need to create chemically and then you create that shape.

Whereas, these, their shape already has a structure that's connected to a function and we know that. So, we -- you know, what will happen in chemistry is they'll tweak around the edges of something to see if they can modify the

function to enhance its ability to be taken orally or its ability to bind or its ability to turn things on.

Whereas, here, you start from scratch and try to build something that specifically binds exactly like you want it.

Back when I was training, we had to actually just do a lot of practice and failures. But now, you can actually build synthetic molecules that bind, you know, in a computer to a receptor.

Q. So, are these drugs -- are these, the molecules that form the drugs, are they regulated, to your knowledge?

A. Yes, very much so.

Q. How so?

A. Well, the -- in the United States, they're regulated under the DEA and, specifically, a scheduling, a class of schedules. You know, Schedule I would be illegal drugs that have an addictive potential or significant harm potential and no medical identified use.

And then, the Schedule II, which is where most of these live, it means that it has a high addiction potential, but they've identified a medical use for it.

And then, Schedule III is that they've identified a medical use and it's less risky. And that's where codeine and that's where Buprenorphine is, III.

The rest of these, morphine, heroin, oxycodone, hydrocodone and Fentanyl, all Schedule II.

Q. All right. So now, getting to validate what I said yesterday, are you familiar with the molecular structure of opiates?

A. I am, yes.

Q. Can you describe for the Court the molecular structure of opiates?

A. Well, the molecular structure of opiates has a -- kind of a core structure and then everything around it is just kind of the accouterment of that structure, meaning it's just kind of added on little pieces around that. So, the core structure for that is what we call the morphinan molecule. And the morphinan alkaloids is a class of drugs that are built off of this basic structure and I think that -- let's see.

If we look at this structure here, while the flat one doesn't do much, and this just looks confusing, I think -- let me draw this out because this is --

Q. Hold on, Doc. Hold on a second.

A. Right. Sorry.

Q. What is it that we're looking at? Is looks like three hexagons.

A. Well, you have three hexagons and a pentagon connection. So, these -- these are connected. So, you know, benzene rings that are connected. So, the chemistry of this is that you start -- nature will start with this,

add in extra carbon, and then lock it in as it comes around.

Q. All right. So, let's back up one more step. What is it that I'm looking at? It likes like three -- this looks like geometry class. What does this picture intend to depict?

A. Well, it is the -- what we call a 2-D structure of a molecule, which means that if I just want to draw out where the carbons are, then you'll see connection, connection, connection as it goes here. So, it's the -- it is the cleanest version of how the molecules are interconnected.

Q. What about the funny looking thing up top, what's that?

A. This is what we call the space filling adaptation. So, in space, they don't have lines like this. They're all surrounded by electron clouds. And so, when you surround it with the electron clouds in the body and you had a microscope big enough, you would see that it looks like this.

And these gray circles are carbons. These white little bumps on there are hydrogens. And the blue, in this case, is a nitrogen.

And so, this is just saying that it doesn't look like this inside of the actual human body or even, you know, in any shape or form. It looks like this when you add in all of the electrons and that. But this is the simple representation to try to understand the basic construct.

Q. All right. So, when we're going through the basic construct, morphinan, where does morphinan fit into our categories?

A. Well, morphinan is a common structure throughout the semi- -- well, one, the opiates, the naturally occurring opiates, and thus, the core structure within the semisynthetic opioids, as well.

Q. So, this morphinan structure, this core structure, is it common throughout the opioids?

A. Yeah. It is the most common throughout the opioids and, in fact, it is the core of all of the semisynthetics and the naturally occurring opioids, whether it be morphine, codeine, thebaine, this morphinan alkaloid is the class of drugs that really extend from the opium.

Q. So, what are the defining structures that identify the morphinan molecule?

A. Well, I think, you know, the three ring with the nitramine ring here, which is this piece here. So, that's actually another ring that's sticking out of the screen if it was to do that. And if you -- if you were to pull this out and hold it in your hand, what it would actually look like is a T. And that's -- I mean, so it's a -- this would be the bottom of the T and this would be the top of the T. And so, that's really what you're looking at for that molecule.

Q. So, for vernacular reasons, what do we call this? Let's give it -- are we going to call it morphinan? Are we going to call it the molecule? How are we going to talk about it?

A. Well, I think in order to describe the rest of them, kind of "the molecule" is an easier way to talk about it. I mean, morphinan is the specific morphinan alkaloid, but the minute you start adding stuff to it, the central molecule is probably easier because instead of me having to add o-methyl, transferring, you know, all of those things, I think we just call it the molecule and move on.

Q. All right. Now, let's go to morphine.

A. All right. So, if we look at morphine again, here, you can identify all of the same rings that we have with a couple of additions. And so, I'll just trace it out, not to be redundant, but just to make sure that we're all seeing the same thing.

So, we have one, two, three -- and then, again, four that sticks out. And if you look here, again, you see this same piece and, again, if we look at it, what we're seeing with this is the -- it goes through here and then, through there, the T is just rotated over as we've added it.

Q. So --

A. It's messy. And then, what we've added here -- so, that's the basics. I'm going to clear it off real quick.

That was the wrong one.

MR. FARRELL: Yes. We need to -- can you get the slide presentation back up?

We still have it up on the big screen.

THE WITNESS: So, if we're looking on the big screen, the biggest piece of the pull-out is if you look at the core molecule and you see the three red oxygens, and those three red oxygens are the things that were added from morphinan to turn it into morphine. And the big piece is if you look at the top and the bottom where we have those hydroxyls, those two oxygens at the top, those are the areas where the vast majority of manipulation and modification of these drugs happens both naturally and in the semisynthetic pathway.

MR. FARRELL: All right. So, I'm going to get Gina to hit the input button. She tells me if we hit HDMI -- it's not up on the screen. This is why corkboards work better. There is no HDMI two up there for me.

There we go.

BY MR. FARRELL:

Q. All right. So, getting back on track, let's not play with it. Let's just --

A. I'll just circle small things and stop being cute.

Q. So, real quick, point to the core molecule within the morphine molecule on this screen.

A. So, this is the core molecule as it sits right in here. And, again, you have one, two, three, and then you have the nitramene ring here. And onto that, we've added hydroxyl connecting oxygen and another hydroxyl group.

So, the important piece to understand is that the substantive shape of this molecule hasn't changed. We've added some things to it but, ultimately, the substantive -- you know, what this molecule really still looks like is still a T in space.

Q. All right. So, now let's move on to heroin. You can erase the screen. Hit the eraser.

A. It did last time, but --

Q. There we go. Now, let's start real simple again. Identify for the Court the core molecule within heroin.

A. So, again, here's the morphinan ring. Those three rings, with the fourth being here. And then, again, if you look here, we have onto these octogens added an acetyl group. So, this is what creates diacetyl, meaning two, morphine, which is heroin.

So, we haven't modified the core structure of the molecule at this point. We've changed a little bit of the electrical field around it but, again, we still end up with when you take the shape of this molecule and you hold it in your hand, you're still going to see something that looks like a T.

Q. All right. Now, I'd like to compare side-by-side morphine molecule to heroin molecule and point out for the Court the similarities and the differences.

A. Well, the similarities again start with the basic structure, the morphinan alkaloid, which is, again, just these -- these four rings, the combined Octogen that rotates it in. And then, the difference is -- the only differences are the addition of an extra acetyl group on the end.

Q. Now, we're going to move on to the semisynthetic opioids and I'd like to go to oxycodone first. Can you identify the core molecule in the oxycodone molecule?

A. Yeah. So, again, it's this morphinan alkaloid where we have these three. And then, you have this nitromene as it comes out.

And then, we go back to what really looks like morphine and then we've added a hydroxyl group here. So, an extra little -- this little red dot here.

But, again, the overall structure, again, that T shape that exists there, has really not changed. So, we still have the T structure that sits there.

What we've changed when we've added a little bit of oxygen is how quickly something can be absorbed into the body, or sometimes a little bit of potency. But, ultimately, structure in this case is negligibly different than heroin or morphine.

Q. So, if it's a difference -- well, first, let's back up. What's the defining molecular structure of oxycodone that differentiates it from heroin and morphine?

A. The two pieces are here, is this hydroxyl group, and then, we've double bonded an Octogen. And those are the only real two substantive changes.

Q. So, why does that make a difference?

A. Well, it doesn't as far as the function on the receptor with the exception that it increases potency. So, it's 1.5 times the potency of morphine. So, it turns that receptor on higher than what morphine would. And then, it absorbs more than twice as good as heroin if it's taken orally.

Q. And is that because of its molecular structure?

A. It is, because structure -- as we state all the time, structure equals function.

Q. So now, let's go on to the hydrocodone molecule. Will you start off by identifying the core molecule within hydrocodone?

A. And so, again, we have the morphinan ring system here, which are these three and then the four. And, again, this is basically oxycodone without the oxygen, so we have -- and so, substantively, again, we're still looking at a situation where we have a T. And this is important because, when you change a structure, if it changes too substantively, it's not going to have the action that it was supposed to have

because, again, structure is function. And so, all of these are going to have the same basic structure, which means it's going to have really predictive function.

Q. All right. So what is the core molecular difference between hydrocodone and oxycodone on this slide?

A. Just this change here.

Q. And what's the difference that change makes?

A. In this one, it actually decreases potency a little bit, but that's it. It doesn't really change absorption, what we call bioavailability, which means that the amount that you take, the percentage that's taken up into the body per pill you take.

So, for oxycodone, it's around 80% of that is absorbed. For heroin, if it's in a pill form, it's only about 40% it's absorbed in the stomach. So, it changes a little bit.

Q. So, let's do this now. I think I got this in the right sequence. Can we compare heroin, hydrocodone and oxycodone?

A. Yes. Yes, we can.

Q. All right. So --

A. And --

Q. Before -- before we go any further, let's erase the screen. Can you hit the eraser?

A. Oh, yeah.

Q. Good. All right. Now, before we go any further, identify for the Court the core molecule between heroin,

oxycodone and hydrocodone.

A. Well, if we start back here on heroin, again, you have the four-ring morphinan structure. You have the central binding oxygen. And then we have the oxygens here, the acetyl groups that are there for diacetylmorphine. So, again, the difference between heroin and morphine is just the addition of these two.

And then, on oxycodone, we have the same core structure as you come here, again, with the binding oxygen; again, with the same, you know, basic shape and the addition of the oxygen here. And then, just a double bonded oxygen. So, basically, removal of the acetyl groups and then the addition of an oxygen.

And if we go to hydrocodone, we can identify these next to each other and, really, the only substantive difference is the change in the oxygen and the hydrogen. So, again, leaving us with a structure that very much still functions in the same way.

Q. All right. So, Dr. Waller, when we're describing the core of each of these three molecules, I want you to randomly pick -- that's not the right word. I want you to use your expert opinion to pick a word. Give me an adjective that describes the core molecule within heroin, the core molecule within oxycodone, and the core molecule within hydrocodone.

A. Well, they're the same.

Q. How same?

A. The molecular structure and shape equals that you have the same structure, which gives you the same function, which gives you the same predictable outcome.

Q. Is the core molecule identical?

A. Yeah. The core molecule is absolutely identical.

Q. All right. Now, let's talk about function. What's the functional similarity between them?

A. Well, all of these bind to the mu -- or two opioid receptors. The mu opioid receptor is the main target of these. And, in that, I think it's important to understand kind of what it means when we say bind to this. And this is, again, a closer look at what we looked at that was the knee joint with the tennis balls, you know, earlier.

If you look here, in a normal state, you have an internal chemical that binds to a receptor and gives you your normal function, right, whatever that function may be. Here, we have an agonist drug, meaning it turns on.

I would say my eight-year-old is the agonist to my ten-year-old pretty much all the time. And then, when they bind, you get this enhanced cellular activity. And that enhanced cellular activity depends on how tightly it binds, how much it turns it on. We have terms for those, you know, affinity, and potency, and things like that.

But, ultimately, it's how tightly does it grab it and how much does it turn it on. And then, that gives you this here.

And then, an antagonist, you've heard of this drug Narcan, naloxone. It is the drug if somebody has overdosed on, you know, heroin or oxycodone that you give them that shot and it knocks it off and blocks it and so it wakes them back up because they can breathe again. And so, that's an antagonist.

So, here would be the endogenous opioids. Here would be the exogenous opioids or opiates. And then, here would be Narcan that would block those, those drugs.

Q. All right. So now, the home stretch for the molecule. Can we compare the difference between the endorphin molecule and say the oxycodone molecule and explain to the judge the functional difference?

A. Well, again, to remind you that this is the basic structure of this, but when we're looking at it all blown up on the screen, it doesn't really do it justice because if we start to move it and actually look at it and how it fits next to an endorphin molecule, it has really no comparison. I mean, it is this little, bitty, tiny thing that binds to one little small portion of a receptor, has no co-response. You can't modify it, can't change it. There is no subtlety to it.

And so, ultimately, as we get to here and we see that this is the molecule that we're hoping is going to have the same effect as an endorphin, or even enhance the work of endorphins, it doesn't do that because if this one is in the system, the endorphin can't do its job. So, we're actually supplanting the natural mechanism when we give these medications. Yet, there's zero capability of modification and subtlety both in location and intensity.

Q. Is the semisynthetic molecule an adequate replacement for the endorphin molecule?

A. Not even close, no.

MR. FARRELL: All right. Judge, at this point, we're going -- you can take your seat. We're going to transition to the next segment, in case you wanted to take a brief recess.

THE COURT: Well, it's a little early, but maybe we can. If this is an appropriate place to do it, we'll be in recess for about ten minutes.

(Recess taken)

(Trial resumed at 10:11 a.m. as follows:)

THE COURT: Dr. Waller, you're still under oath and we may proceed.

MR. FARRELL: Paul Farrell, Jr., F-a-r-r-e-l-l.

BY MR. FARRELL:

Q. Welcome back, Dr. Waller. When we left, we were

talking -- we had the structure equals function that produces outcomes. And we've talked about the structure and the function. Now I'd like to go to the outcomes.

Are there -- in general, are there negative consequences to the function of these molecules?

A. Sure.

Q. Can you describe them?

A. I'd say the most stark negative outcomes would be overdose, death and addiction.

Q. All right. Let's start off with addiction. Can you tell the Court what, what is addiction?

A. Well, addiction is a -- and it's -- we have definitions for it and I'm happy to answer on my own, but I think that it's defined philosophically by the American Society of Addiction Medicine as, you know, a treatable chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences.

This is the more philosophical approach to the description of this. And we also have other definitions that are meant to be diagnostic in their approach.

And that one would be more of the, what we call the *Diagnostic and Statistic Manual V* from the American

Psychiatric Association which begins to delineate the specifics of those things so that we can quantify them.

Q. Hold on a second. Let's slow down.

So we talked about the definition of addiction. And now we're moving into the medical term or the diagnostic term. What is that diagnostic term?

A. Well, for opioids it would be opioid use disorder.

Q. What is opioid use disorder, or OUD?

A. Well, it's the, the dysfunctional utilization of that -- of an opioid where it impacts a number of aspects of someone's life. And it's broken out into 11 specific criteria, but the general concepts are -- there are components about how you have a loss of control over the utilization of that substance. You have a significant social impact from that use of that substance. And you have harmful effects to yourself from that substance.

And then there are two medical pieces of that definition which talk about things like tolerance and dependence, which for those on a prescription version of this don't factor into the conversation, but we can discuss that if we need to later.

MR. HESTER: Your Honor, Timothy Hester. May I object? Slides are being placed up on the board as the witness is speaking. He's asked a question about opioid use disorder, and then 12 points are being put up on the slide

without any indication that he's being shown the document.

THE COURT: I sustain the objection, Mr. Farrell, and you can use the slide when you specifically get to it in your direct examination.

That was your objection, wasn't it, Mr. Hester?

MR. HESTER: Yes, Your Honor. Thank you.

MR. FARRELL: Very good.

Can you take the slide down for a second? All right.

BY MR. FARRELL:

Q. So when we're talking about opioid use disorder, what are the criteria?

A. Opioid use disorder, you know, like most use disorders have 11 criteria. And, again, those are broken into -- the first nine of those criteria are really broken into three sub-contextual pieces. And that has to do with the uncontrolled utilization of the substance.

So you're taking it longer, you know, than expected or higher doses than expected. You have an inability to cut back. You know, you have a craving for it.

And then you look at the next grouping of that which really talks more about the social impact, the failure to complete your normal social roles, you're losing friendships, you are, you know, being fired from work.

And then it gets into the harmful -- you're using it despite harmful use, meaning you may get an infection or you

may use, you know, what would be a, you know, a needle that somebody else has already used knowing that harm.

Q. So without going through each of the factors, the term "addiction" is a term used in pain, pain management in medicine. It has a definition from the American Society of Addiction Medicine; correct?

A. Correct.

Q. All right. Now, there's also a clinical diagnosis, but we don't call it addiction, do we?

A. Well, there are certain components. So I think the best way to talk about it and understand it is that addiction is the umbrella term that we would utilize.

Within addiction, we have substance use disorders. So that would be opioid use disorder, alcohol use disorder. And then we have behavioral addictions, gambling, gaming. So there -- that's the delineation.

So all of those live under the umbrella of the definition and the term "addiction."

Q. So within opioid use disorder itself, are there commonalities used for that particular diagnosis?

A. Yes. And, again, based on the, the *DSM V*, the *Diagnostic and Statistic Manual V's* definition, which I agree with in general, the -- there are nine criteria that help us define the behaviors associated with it, and then two physiologic phenomenon associated with the diagnosis as

well.

Q. All right.

MR. HESTER: Your Honor, I'm sorry to interrupt. The same objection. The slide is being placed up with a number of points that the witness hasn't spoken to yet.

THE COURT: Yeah, I agree, Mr. Farrell. I'll sustain the objection.

MR. FARRELL: All right. So I don't have the clicker in my hand, so what we'll do is we'll leave it off until I specifically address the slide. Thank you. I apologize.

THE COURT: We'll see if that's acceptable.

MR. HESTER: Thank you.

BY MR. FARRELL:

Q. All right. So opioid use disorder, and you described some of the behaviors with it. Can this be explained by neuroscience?

A. Sure, absolutely.

Q. How?

A. So when we talk about behaviors, behaviors ultimately are neuroscience. If you make, you know, a decision or you have a reaction or you have a change in your mood or a change in your interaction style, all of those happen secondary to the neuroscience and different parts of the brain.

So as we, as we look at the definition of addiction, I mean, in its purist form, it's -- the neuroscience creates that signal at a synapse or a hundred million synapses that pushes you to have that behavior.

And, so, any modification in that system changes the way in which you would behave in a certain situation. So the neuroscience definitely explains really each of -- all 11 of those criteria.

Q. All right. So what aspect of neuroscience explains why opioids can cause behaviors listed in -- within the definition of OUD?

A. Well, I think the -- the core of this is really its modification of dopamine in the brain. And --

Q. What is dopamine?

A. So dopamine is a, is a molecule naturally produced inside of the brain. It really is responsible for motivation, reward, a mother/baby bond, I mean, happiness.

And it is the -- the dysfunction of the dopamine levels in specific areas of the brain called the reward system is really the crux of all addictive disorders, whether they be a substance use disorder or gambling.

And, so, when we disrupt the normal utilization of that part of the brain where dopamine is made, then we really disrupt all aspects of reward; how we make friendships, how we're motivated, how we interact.

And that's really at the core of the dysfunction and all addiction, and specifically, to your question, opioid use disorder.

Q. All right. So are dopamine -- is this dopamine, is it produced naturally?

A. Yes, it is.

Q. And can it be recreated semi-synthetically?

A. Sure. We use dopamine in L-dopa. We use it to treat Parkinson's Disease.

Q. So I want to talk a little bit about how dopamine impacts the brain. In your field and in your science, have you undertaken some analysis of different dopamine levels in the brain?

A. Yes. This has been kind of my focus area is trying to really understand this, this dopamine theory of addiction. I started many years ago and it's really been solidified as the theory of what creates addiction.

And I spent hundreds of hours digging into, you know, hundreds of articles trying to understand this and, you know, I've been to the NIH and worked with them to understand this.

Q. So have you taught on this subject and lectured on this subject?

A. Often.

Q. And have you created a slide to illustrate the

different -- have you created a slide that demonstrates the difference in dopamine levels based on triggers?

A. I have. And I can describe those without a slide.

MR. FARRELL: At this point, Judge, I'd like to illustrate the slide.

Can you bring up the dopamine one? Very good.

BY MR. FARRELL:

Q. All right. So with the dopamine slide, can you walk through the different triggers and explain to the Judge the impact of the change in dopamine levels?

A. Sure. So let's start with the basics of kind of what normal is so that we can understand what deviation from normal is.

So normal is you get up in the morning and you have your coffee, you go to work. Right? It's the motivation to get out of bed, to get dressed, to have a shower, to show up and do those things.

And in order to have that motivation, you really have to have a baseline level of dopamine. And I can go through how I calculated this. But at the end of it, it's about 50 nanograms per deciliter. All right? So it's this amount. This is the amount that you need to kind of get up and go somewhere and that's your normal day.

Q. So let's quantify this since we're creating a record. What would you quantify as dopamine levels on a,

quote/unquote, normal day?

A. Do you mean by the amount and where it is?

Q. Yes.

A. So that would be 50 -- so I have to say so from different studies, there are a whole bunch of different ways that they describe this. They look at things that sit in the synapse and things that sit there.

So this is a construct of all of those studies kind of combined stabilized out to a number of nanograms per deciliter because they all reported different levels. So you have to go through it and equalize them and all that.

And when you do that, what you find is -- across a multitude of studies, we find that in this reward part of the brain -- and that has a specific name. It's called the nucleus accumbens. But in that --

Q. I'm going to ask you as a favor, and this is going to make me the favorite of the court reporter, to please slow down, especially when you use words that regular people don't know.

A. Fair enough. So in the reward system there is a specific area called the nucleus accumbens. NAc is how it's -- the NAc is how we kind of define it. And in this place, it releases a certain amount of dopamine to get our normal day. And that's -- it releases that and it creates that motivation. And you can have, you know, what's

considered a bad day, you know, so --

Q. Stop right there. On the screen you've depicted a dopamine level of somebody on a normal day. And have we quantified it yet? You said 50 I think.

A. Yeah, 50 nanograms per deciliter.

Q. Okay. Now, have you also undertaken to identify or, based on your research, what the dopamine levels would look like on a terrible day?

A. Yes. And it's around 40 nanograms per deciliter.

Q. So explain to me what's the difference -- how is the body differently reacting on a normal day from a terrible day that results in a drop of 10 nanograms of dopamine?

A. Well, the difference between those is one day you actually get up and have your coffee and go to work, and the next day you think of 500 reasons you're going to not go to work.

It's the, "I'm not going to motivate to get out of bed." It's, "I'm going to call in sick. I'm going to go do these things." And in some cases it's, "I'm not going to get out of my pajamas. I'm not going to show up for an appointment. I'm not going to --"

Q. So, now, let's talk about the best day ever. What would be the approximate dopamine level if you had the best day ever?

A. Well, the best day ever, and that's different for

everybody I guess, but, you know, the day that you win the lottery, own an island, have two percent body fat kind of all at once, you know, that's the best day ever. And that would get you up to around 100 nanograms per deciliter.

Q. All right. So what I want to figure out is in your brain, you're having a normal day and you hit the lottery. What's going on chemically in the brain that raises dopamine levels?

A. Well, clinically in the brain, you have -- there's a lot going on. But in the reward center in the brain, you're going to have an increase in the release of dopamine. And the, and the nucleus accumbens and another area called the ventral tegmental area.

Q. Hold on. The court reporter is going to need that again. So let's use those two words again but slowly.

A. Nucleus accumbens and the ventral tegmental area.

Q. Very good. All right. So what's going on in those parts of the brain?

A. Well, in those parts, it's, it's releasing the normal high of dopamine that we get. Right? And the -- when it does that, it actually goes to places -- other parts of the brain such as the amygdala. And in the amygdala it decreases -- well, it will increase serotonin and decrease the part of that area that creates fear.

So you now have not only happiness and motivation, but

you have a decrease in fear. And it implants a memory. It allows us to impart what we call an emotional memory into a different part of the brain.

So it has a cascade of effects and it's not just making you happy. It actually does a lot of other stuff.

Q. So let's, let's kind of tie together different pieces.

We're talking about the endogenous chemicals in the brain and what dopamine levels look like on good days and bad days and the sound board.

Can you explain to the Court how these natural molecules that we designed are interplaying with all of the different sound board analogy you gave earlier?

A. Well, the problem is is that the chemicals -- the internal chemicals do use the sound board. They allow you to be elated, but not be abstractly illogical and make really bad decisions.

Q. Why? How?

A. Well, because they only release those signals in the specific area that the body needs at that moment.

Q. Is that why the endogenous molecule structure is so complicated?

A. It has to be that complicated, yes.

Q. Okay. Now, let's talk about the difference when you have artificial dopamine levels or dopamine levels caused by opioids.

Have you studied what the approximate dopamine level would be when you take a semi-synthetic version orally or otherwise and what it does to the brain?

A. Yeah, I've studied all the research in this area specifically on the brain. And --

Q. Well, hold on. Just, yes, you can.

A. Yes.

Q. So now I've got to get to the follow-up question which is, which is: Can you demonstrate on this graph the comparative between the dopamine levels on opioids versus a person's dopamine levels on their normal day or best day?

A. I can.

Q. So what would be the quantity on this chart of the dopamine level on opioids?

A. For opioids it's around 900 nanograms per deciliter.

Q. Why? Tell me why it is that the semi-synthetic opioids have such a dramatic difference in dopamine levels from the endogenous molecule that we naturally produce.

A. Well, it goes back to the analogy of talking about the difference between the sound board and the volume knob.

And, so, when you give this chemical -- it has one job and that is to bind to a specific area on the receptor and turn it up as high as it will go.

And when that occurs, it also doesn't have the subtlety of knowing when to let go. So when it's on, it's on there

for what we call the half-life of the drug.

And, so, if the drug is there for a long time, it's just going to sit there on the receptor and not leave. And other body mechanisms can't kick it off.

And, so, with that, the dopamine gets released and released and released and it spins up to the point where it hits this maximum piece that's far above what the normal day would be, what your best day would be. And there's predictable issues when that happens.

Q. What kind of predictable issues?

A. Well, at the time what you identify is that the first time that you take a --

Q. Hold on. Hold on. In general, what kind of consequences happen -- we're talking about the difference between the sound board and turning the volume on, on and off and on and off.

A. Right.

Q. What are the types of consequences generally of repeatedly adjusting the volume from high to low to high to low?

A. Well, what the body is going to want to do is not let you turn it up as high anymore.

Q. Why?

A. Because when it gets up that high, it loses all capability to deliver subtlety in the body systems.

Q. All right. So let's stop there for a second. Have you studied in the brain what happens through neuroscience through repeated exposures to opioids?

A. Yes.

Q. Okay. Have you prepared a slide that demonstrates the difference from the first exposure to repeated exposures?

A. I have.

Q. Would that be helpful to you in explaining to the Court the consequences or effects?

A. Visually, yes.

MR. FARRELL: Judge, I'd like to provide the next slide.

BY MR. FARRELL:

Q. All right. Explain to me what is this? What are you trying to communicate with this slide?

A. So if we look at a person who ultimately first took opioids and we had this large rush of dopamine out to 900 nanograms per deciliter, the brain doesn't like to be kind of told what to do. So it begins to re-regulate the system.

So that will be the highest point ever because the brain immediately after that first dose of that opioid will not make that much dopamine again. It won't release it. And that's what a lot of my patients would label as chasing the dragon. They can never get that same initial high.

And the reason is because immediately, the body has decreased the amount of dopamine. It won't ever release to that same drug again. It learned its lesson. But if you continue to use it, it's going to turn down the amount even more continually.

And not only does it actually turn down the amount of dopamine that it makes, but the amount of dopamine that's released. And then over time, the neuron that releases it will atrophy.

So it will, it will shrink the neuron because it thinks, "I don't need to make more natural dopamine because this exogenous thing is doing it for me."

And we have good research to show that over time, if you continue to do that, there's a sub population that it will literally give up even trying to support this nerve and kill it.

And, so, we have people -- it's called leukoencephalopathy and --

Q. Hold on, big word.

A. Sorry.

Q. Leuko?

A. Encephalopathy.

Q. Encephalopathy, all right. What is leukoencephalopathy?

A. This is a phenomenon that we've identified in opioids

when taken in a subset of the population where that signal is so strong to decrease the dopamine that the body begins a process of what we call apoptosis.

Q. So let's take a look at this slide. Tell me what we're trying to depict in this slide. What is the orange line?

A. The orange line is the repeated dose of the substance. So it goes up and then it goes down when you're off the substance. It goes up and then it goes down.

And over time, the body will continually decrease the amount of dopamine even available to be released until you ultimately get to a person who is -- and I hear this from my patients all the time, that they're only using to feel normal because they can't even get out of bed. They can't do their -- any daily work. They can't interact with people.

Q. Let's stop and talk about this difference right here.

When we're getting down here -- and I'm pointing for the record to the latter half of the right side of the exhibit -- the orange line seems to obviously start out well above the normal blue line and then ends up prolonged depressed below the blue line.

What's going on here at this transition point?

A. Well, what happens at the transition point is as we come down and that flattens out, this really represents -- let's say the best thing happens. We identified that

somebody has addiction and we want to remove them from that substance.

When that occurs, their dopamine doesn't just bounce back. Their motivation doesn't just come around. And, so, we now have someone that not only has injured that part of the brain, but now their normal set point is well below even your worst day.

So behaviors associated with having dopamine at this low level are, "I'm not going to call anybody. I'm not leaving my house. I'm not getting out of my pajamas," you know.

And those, those behaviors that were so frustrating to me as an ER physician when I was first starting out really become well explained when you look at the, the lack of capability to produce dopamine. And dopamine is the required chemical to create motivation.

Q. All right.

THE COURT: If you get clean, will the ability to produce it come back?

THE WITNESS: That's a great question. And this is something that for the vast majority of patients, the answer is "yes."

Some of those have had a permanent injury and they'll require treatment in an on-going fashion. But we find that most people, especially the younger we identify them, the

more likely that dopamine is to come back and to be happy like the dopamine I had when I saw my ten-year-old hit a double yesterday, you know, on Zoom. That's -- that was dopamine. That was great.

They don't have that ability in this state for a while. It takes sometimes years to get that back. And the great news is we can, but it does require very specific interventions and treatment.

THE COURT: Does the brain react the same way to other addictive substances like alcohol, for instance?

THE WITNESS: It does and to varying degrees. Some will go a little higher, some a little lower. But the final common pathway for all addictive substances and behaviors is really this dysregulation of the dopamine pathway.

And, and this is germane to the identification of what is going to be an issue with someone else. And, unfortunately, we don't have yet the ability to actually measure dopamine in people walking down the street or coming into the office or recognize any risk of how high it's going to go.

And, so, we do know that whatever that behavior, or whatever that substance is, the longer they take it and the higher the kind of dosing of it that they get, whether it's an opioid or gambling, the more that it's going to

significantly decrease over time.
BY MR. FARRELL:
Q. So for triggering purposes, what I'd like to understand is this, this dopamine reaction, are there commonalities in this reaction between the use and abuse of, of semi-synthetic opioids such as that are prescribed, hydrocodone and oxycodone in particular, and heroin?
A. Yeah, absolutely because they're both opioids.
Q. All right. So when we take the two and we compare it to, say, the alcohol abuse, is alcohol abuse the same as these triggers with heroin, oxycodone, and hydrocodone?
A. Yeah, the same fundamental action occurs in the central axis.
Q. From a cause -- from a commonality standpoint, are there classifications or similar reactions based on neuroscience?
A. Yeah, the neuroscience would say that for alcohol it has a little less of an impact on the dopamine than do opioids, but it has a predictable significant increase requiring a response from the body. Things that -- nicotine, marijuana, all of those disproportionately raise that.
But opioids, you know, really -- and it doesn't necessarily matter how you use certain ones. It has to do

with potency and amounts and the timing of use.

Q. So using these models that we've talked about before, in your research and your expertise, is there commonality between an addict's physiological response to hydrocodone and oxycodone on one hand and heroin on the other?

A. Physiologically it's a dose dependent phenomenon, not a drug dependent phenomenon.

Q. What about the neuroscience?

A. Same neuroscience.

Q. So from your experience in science, is there an explanation -- or let me back up. In your experience, have you seen hydrocodone and oxycodone as a gateway to heroin?

A. I don't use a gateway. It's no different. I mean, for some people it doesn't -- it's no different for them because when they take oxycodone or hydrocodone, for them if they have that same change in the brain chemistry, they might as well have taken the other. It doesn't matter. It's an opioid that binds in the brain disproportionately releasing this dopamine and causing the same behavioral phenomenon with this need to search for dopamine.

Q. So that's a critical point for me to follow up on. Does the brain know the difference between whether or not this is hydrocodone, oxycodone, or heroin?

A. It has no idea.

Q. Is it the same mu-receptor that is receiving the same

neurotransmission?

A. Yes.

Q. And, so, the reason it's not a gateway in the brain is because it sees it as identical?

A. Yeah. So this is an artificial phenomenon that people in the '70s and '80s tried to come up with around this, quote, gateway theory. But it's not a gateway theory really. It's just a -- the same -- the drug -- to your point, the brain doesn't know what drug you just gave it. It just knows the action that it has.

And that action is directly related to the structure. So if the structure is similar, the function is going to be the same. All it knows is that the mu-receptor got turned on. That's it.

Q. What else turns on that particular mu-receptor?

A. Hydrocodone, oxycodone, morphine, thebaine.

Q. Why is it call the mu-receptor?

A. Well, it's a mu-opioid receptor. It's just the mu version of an opioid receptor.

Q. So we're talking about the turning on of a specific receptor called the mu-opioid receptor and it can be turned on by oxycodone, hydrocodone, and heroin?

A. Correct.

MR. HESTER: Objection. He's leading.

MR. FARRELL: I'm summarizing, but I'll retract,

Judge, and rephrase.

THE COURT: I'm sorry. I was making a note.

MR. HESTER: Sorry, Your Honor. I object to leading.

THE COURT: Sustained. Don't lead the witness, Mr. Farrell.

MR. FARRELL: Yes, Your Honor.

BY MR. FARRELL:

Q. So the mu-opioid receptor, what are the different opiates, semi-synthetic opiates that it receives?

A. Whichever one is put in the body.

Q. Okay. Now, I want to talk real briefly about a different thing, fentanyl. You said fentanyl was synthetic?

A. Correct.

Q. How does fentanyl play into this picture?

A. Well, structurally it's, it's different looking than the morphinan based molecules. However, if you were to line it up in its electrostatic form, the electron cloud form that we looked at, it still has to bind the same receptor which means it still has to pick points that it's going to attach to that which then, quote, turn on the receptor.

And, so, fentanyl happens to do this in a way that turns the receptor up about as high as you can get it. There are only a couple of other drugs on the market that turn it up a little bit more. And those are still in the

same family. Sufentanil would be one we use most often in the hospital.

Q. Let me ask you this. Why is it that these different molecular structures turn on the mu-opioid receptor to varying degrees?

A. So this has to do with what we call stereotactic orientation. I'll explain what that means.

So what that means is that if I have a lock and a key, you can have a subtle change to the key and still open the lock. Some keys are perfect and it slides right in and it easily rotates. Some are good enough and it turns it on.

And, so, the varying degrees between this, all these keys open the same lock. It's just exactly how it fits inside of the lock.

Q. All right. So for purposes of fit, what is the -- which of these molecules has -- or can you rank these molecules in terms of that perfect fit in the lock of the mu-opioid receptor?

A. Well, the fit in this off-the-cuff example would be around affinity meaning how, how, how much -- I mean, the word affinity is pretty descriptive but, you know, how closely does it match exactly what it needs to bind.

Fentanyl would have the highest affinity to the mu-opioid receptor. And then we look at oxycodone, heroin, hydrocodone, and morphine are about equivalent as far as

which one grabs it the tightest or fits the neatest in there.

And then you have the next piece which is called potency meaning how, how quickly does it open that lock, you know, how wide does it open the door.

And that potency would be, again, fentanyl would be most potent followed by -- of the ones you gave me -- there's a laundry list of opioids. But if you look at fentanyl, it would go fentanyl, oxycodone, hydrocodone, morphine, and codeine below that.

Q. All right. So I want to kind of wrap up and just address right off the bat this mu-opioid receptor in the brain. Is it fair to say that its job in the brain is to receive opioid neurotransmittals?

MR. HESTER: Objection to leading.

THE COURT: Sustained.

MR. FARRELL: Okay.

THE COURT: Try not to lead him, Mr. Farrell. I know it's difficult but --

MR. FARRELL: I'm really just trying to wrap up and make points that are in my favor.

THE COURT: Yeah.

BY MR. FARRELL:

Q. So what I'd like for you to do is -- I'm trying to imagine if I win the lottery, is that going to turn on

the mu-opioid receptor?

A. Indirectly, not directly.

Q. How? How would it indirectly?

A. So indirectly when we talked about the cascade of dopamine in like those happy moments, it also increases the release of endorphin which binds the mu-receptor which directly turns on more dopamine.

So opioids will bind to the mu-receptor whether it's your endorphin that gives you a runner's high or whether it's morphine or whether it's oxycodone or heroin. It doesn't matter. It's just different degrees of how rapidly, how much it binds, and how much it turns it on.

But the concept is that the opioid receptor, when it is activated, one of the places that it works is in this reward system. And, so, when I bind it and it, quote, turns on, the action that it creates is a release of dopamine.

If that's subtly done from endorphins, our internal, you know, molecules, then it is a subtle increase in dopamine. It is the: Me jumping up and down in my hotel room watching my kid hit a double, you know, dopamine.

But then it turns off and you do what you're going to do. It doesn't do anything else. That's its job at that point.

If I bind that and turn it all the way up, then what I get is a disproportionate response of that release of

dopamine. It has no real control over it. It's not -- it's a car that has the gas pushed to the, you know, the ground and just let go without a driver. I mean, it doesn't have a specific path that it's following.

Q. All right. So in your opinion, is there a molecular -- from a molecular standpoint, is there an explanation or a link between oxycodone/hydrocodone on one hand and fentanyl on the other from a molecular standpoint?

A. Sure. Well, molecularly they have the same what we call fit form. So the fit form is, it fits into a receptor. It has the right form to fit into a receptor.

Q. And, so, the answer is "yes"?

A. Yes.

Q. And do you hold that opinion to a reasonable degree of certainty?

A. Yes.

Q. All right. Now, from a function standpoint, is there a link, a causal link between the oxycodone and hydrocodone on the one hand and heroin on the other?

A. A link between the utilization of one and the other?

Q. The function.

A. Yeah, the function is, is the same with the varying degrees of how tight it binds or how much it tweaks it. But ultimately the function is the same.

Q. And, so, the answer is "yes"?

A. Correct.

Q. The answer is "yes" -- the correct answer is "yes"?

A. Yes.

Q. So the answer to my question is "yes"?

A. Yes.

Q. I'm just trying to get the record. And to a reasonable degree of certainty do you hold that opinion?

A. I do.

Q. Now, so we have structure equals function equals outcome.

The outcome of oxycodone and hydrocodone and the outcome of the heroin on the mu-receptor while differing in degrees, is there a relationship between the two?

MR. HESTER: Objection.

THE COURT: I'll overrule the objection that time.

Can you answer the question?

THE WITNESS: All right. So the two -- they do the same thing when they hit the mu-receptor within a very small degree of difference.

In a sense, back to the -- the point is the receptor doesn't know what's on it. It just knows it's being turned on to a certain degree.

And, so, whether it's oxycodone or whether it's heroin, it doesn't matter. It just binds to the mu-receptor and turns it on. And --

Q. So the answer to my question is "yes" or "no"?

A. Yes.

Q. And do you hold that opinion to a reasonable degree of certainty?

A. I do.

MR. FARRELL: Give me one second, Judge, please.

(Pause)

MR. FARRELL: Thank you, Judge. We'll pass the witness.

THE COURT: All right. You may cross-examine.

MS. WICHT: Thank you, Your Honor. I know we'll have to switch things over. I defer to the Court if you'd like to take a short break to do that or --

THE COURT: I'm having trouble understanding you with the mask on.

MS. WICHT: I'm sorry. Thank you. Sorry, Your Honor. We'll need to switch over the feed and things like that. I just defer to the Court if you want to take a momentary break while we do that.

THE COURT: Let's keep it real short. But if you need a break to do that, that will be fine.

MS. WICHT: Yes. Thank you, Your Honor.

THE COURT: Keep it to five minutes if we can.

(Recess taken from 10:50 a.m. until 10:55 a.m.)

THE COURT: You can resume the witness stand, Dr.

Waller.

You may proceed, Ms. Wicht.

MS. WICHT: Thank you very much, Judge.

CROSS EXAMINATION

BY MS. WICHT:

Q. Good morning, Dr. Waller.

A. Good morning.

Q. My name is Jennifer Wicht and I represent Cardinal Health and I'll be asking you a series of questions and then others from the defense may ask you some questions as well.

A. Okay.

Q. Dr. Waller, you testified this morning about the molecular similarities of opioids like oxycodone and hydrocodone and heroin; correct?

A. Uh-huh, yes.

Q. I want to start by asking you about some differences among those things. You understand, of course, that oxycodone is an FDA approved medication; correct?

A. That is correct.

Q. So the Government has authorized the manufacture of oxycodone in the United States; right?

A. Correct.

Q. And the Government has decided what warnings, or has approved what warnings need to be placed on the label of oxycodone?

A. On the label, yes.

Q. And oxycodone is allowed to be prescribed in the United States by trained and licensed and registered medical professionals; right?

A. Correct.

Q. And oxycodone is allowed to be dispensed by trained and licensed and registered pharmacists in the United States; correct?

A. Correct.

Q. As long as it's to a patient who has a valid prescription; right?

A. Sometimes.

Q. Is it your opinion that oxycodone can be dispensed to a patient who does not have a prescription?

A. It wasn't about the prescription. It was about the term "legitimate." But --

Q. Okay. But you agree that if a patient presents a legitimate prescription, a licensed, registered, trained pharmacist is permitted to dispense oxycodone; correct?

A. I would agree that if they present a prescription, again just to the point of "legitimate."

Q. Okay. Thank you. And that's because the Government, the FDA, DEA, perhaps others have determined that there is an appropriate medical use for oxycodone; correct?

A. Well, I would say in one respect, yes.

Q. And those same things are all true of hydrocodone as well; correct?

A. Correct.

Q. Now, heroin, on the other hand, is an illegal drug in the United States; correct?

A. Currently.

Q. Currently. It can't be legally manufactured; correct?

A. For research it can, but it's -- yeah.

Q. Not for -- it can't be legally prescribed to a patient for medical purposes; correct?

A. Correct.

Q. And it can't be illegally dispensed by a pharmacist; correct?

A. Correct.

Q. So whatever the molecular similarities are between oxycodone and hydrocodone, opioid medications like heroin, it's clear, you would agree, that the law treats that very differently; correct?

A. Based on the schedule, yes.

Q. And you mentioned the schedule and I want to just follow up briefly on another drug that we discussed which is fentanyl. And there are -- there is both legal scheduled fentanyl and illicit fentanyl that exists; correct?

A. Yes.

Q. And there's legal fentanyl, which is a scheduled drug

legal to manufacture and prescribe; correct?

A. I think I need a little more instruction on the term because fentanyl is just a chemical, so legal versus illegal is -- it doesn't have a meaning from a chemical itself, so I'm wondering if you could help me just to describe what you mean by, quote, legal versus not legal, --

Q. Okay.

A. -- at what point that happens.

Q. Okay. So the chemical fentanyl has been approved by FDA as legal medication in the United States; correct?

A. In certain forms, yes.

Q. In certain forms, okay. And, therefore, can be manufactured in certain forms in the United States; correct?

A. Correct.

Q. And prescribed and dispensed in those forms in the United States; correct?

A. In most instances.

Q. And there are other forms of fentanyl that are illegal in the United States to manufacture or sell; correct?

A. I would say, yes.

Q. Now, the manufacture of prescription opioids like oxycodone, hydrocodone is heavily regulated; is that correct?

A. To a certain degree. I'm not fully familiar with all the regulations.

Q. Okay. I'm not going to ask you to go into any of the details of them.

A. That's good.

Q. But fair to say that a lawfully and correctly manufactured 10-milligram hydrocodone pill will contain 10 milligrams of hydrocodone?

A. Within a degree of error, yes.

Q. Okay. Whereas heroin is an illegal street drug?

A. I would stop at "illegal."

Q. Does it -- heroin is an illegal drug in the United States?

A. Sure.

Q. So the creation of heroin is not regulated like the manufacture of prescription opioids; correct?

A. Correct.

Q. And heroin can be adulterated with other substances like illicit fentanyl; correct?

A. With fentanyl, yes.

Q. With fentanyl, with the chemical compound fentanyl?

A. Correct.

Q. Okay. And that happens with some frequency. Would you agree?

A. Depends on the geography.

Q. On the other hand, a lawfully manufactured prescription opioid would not be adulterated with the chemical compound

fentanyl; correct?

A. Hopefully not.

Q. Hopefully not, correct. Now, Dr. Waller, you agree -- you testified again about the similarities between oxycodone and hydrocodone and heroin and some of the outcomes that are associated with those things.

But you agree, though, that prescription opioid medications, oxycodone -- like oxycodone and hydrocodone have legitimate medical uses; correct?

A. Yeah, in a sense, yes.

Q. Okay. You are a practicing physician still in emergency medicine; is that correct?

A. That's correct.

Q. And in your own medical practice, you have prescribed opioids to thousands of patients over time; correct?

A. Yes.

Q. And it's your opinion that prescription opioid medications can be effective, for example, in treating acute traumatic pain; correct?

A. Correct.

Q. And prescription opioid medications can be effective in palliative care settings; correct?

A. That's correct.

Q. And you agree that for those patients, the benefits of the opioid medications outweigh -- can outweigh the

potential risks?

MR. FARRELL: Objection, Your Honor.

THE COURT: Basis?

MR. FARRELL: Outside the scope of direct.

THE COURT: Overruled.

BY MS. WICHT:

Q. You can answer, Dr. Waller, if you recall the question.

A. I thought I answered, but do I -- I might have gotten mixed up. You can re-ask and I'll answer.

Q. Okay. You agree -- I think the question I asked was you would agree that for those patients, the benefits of prescription opioid medications outweigh the risks?

A. For acute pain and palliative care, severe acute pain specifically.

Q. Okay. So if someone were to attempt to net out the benefits and the risks of prescription opioids, they would need to take into account those benefits in treating, in your opinion, acute traumatic pain and palliative care; correct?

A. Yeah, the equation requires both of those evaluations.

Q. Correct. Now, it's your opinion that opioid medications should not be widely prescribed to treat chronic non-cancer pain; correct?

A. That is correct.

Q. But, nevertheless, you do believe that there is a small group of patients who legitimately can be prescribed opioids for pain lasting more than three to seven days; correct?

A. That's correct.

Q. So for acute or chronic pain, your view is that opioids could still be medically appropriate, but only as an approach of last resort; is that correct?

A. With some caveats, yes.

Q. And is one of those caveats that it should be at the lowest effective dose?

A. Well, for acute pain specifically it's the -- not only a dose, but also a timing of utilization. So two, three days, you know, for acute pain. And then if you're talking about palliative care, that's a completely different set of risk benefits that need to be calculated.

Q. Okay. Well, I think you did agree, though, that there are some patients who can legitimately be prescribed opioids for pain lasting more than three to seven days; correct?

A. Within the palliative and Hospice care setting, I would agree with that.

Q. And you would agree that that's a judgment that the physician has to make by evaluating the risks and benefits of the medication for the specific patient in front of him or her; correct?

A. I don't agree with that.

Q. You don't agree that whether or not to prescribe an opioid for a patient is a judgment that the physician has to make?

A. Alone, never. It should be a common -- it should be a decision collaboratively made with the patient.

Q. The physician and the patient should collaborate together to make that decision?

A. That's correct.

Q. But a wholesale distributor doesn't collaborate in that decision, do they?

A. Not in that specific decision, just the "what's available" decision.

Q. All right. So I want to talk about the role of distributors in all these things that you've opined about.

So distributors don't determine whether a doctor writes a prescription for a particular patient for oxycodone or hydrocodone or for some other non-opioid pain reliever; correct?

A. No, not at the point of prescription.

Q. Okay. A physician does that; correct?

A. In combination with the patient.

Q. In combination with the patient. Okay. And distributors don't determine what strength of medication the doctor writes for; for example, 5 milligrams, 15 milligrams, 30 milligrams. Correct?

A. Not what they write for.

Q. The doctor in consultation with the patient would do that; correct?

A. Right.

Q. And a distributor doesn't determine whether a patient gets a one-day or a three-day or a 30-day prescription; correct?

A. It depends.

Q. Is it your testimony that sometimes a distributor, a wholesale distributor might decide whether the doctor writes the prescription for a one-day or three-day or thirty-day course?

A. No. It's how it would be filled based on what the distributor made available to the pharmacy in which the patient has access to.

Q. Well, the pharmacist fills the prescription, correct, not the distributor?

A. The distributor makes available what the pharmacist has available to fill. So one doesn't happen without the other. So they can't fill it if it's not available. And if it's not available, it may have different strengths. And those different strengths may need to be then collaborated back with the doctor if these are equivalent or not. And, so, it's not, it's not a linear decision all the time, especially in small pharmacies.

Q. But when a patient presents with a prescription in a pharmacy to be dispensed, the distributor has played no role in whether that prescription calls for a one-day course, a three-day course, a 30-day course or something else; correct?

A. No, not what's on the prescription, just how the prescription is filled.

Q. And distributors don't determine whether a patient will be authorized to refill a prescription; correct?

A. Authorization, no.

Q. And distributors don't determine how many times a patient might be authorized to refill a prescription; correct?

A. Not that I'm aware.

Q. Now, once a prescription opioid is dispensed to a patient, the distributor has no interactions with the patient; correct?

A. Not directly, no.

Q. In fact, distributors don't have any direct interaction with patients at all; correct?

A. Not that I'm aware of.

Q. Now, you understand, Dr. Waller, that wholesale distributors only supply what their pharmacy customers order; is that correct?

A. Or alternatives if they don't have what they ordered.

Q. Okay. But wholesale distributors don't commonly come up to a pharmacy and unload drugs on the sidewalk that the pharmacy hasn't ordered in hopes that the pharmacy will take them; correct? That's not how it works?

A. No. That happens before they get on the truck.

Q. The pharmacy places the order before the medications are placed on the truck; correct?

A. The order, the order is placed. And if those things are not available, then a conversation occurs about what can fill that order if they don't have it, whether it's a generic or a different brand or different dose, you know. And then those play into that whole role.

Q. Okay. So distributors are filling stocking orders for pharmacies to have medication on hand; correct?

A. In one capacity, uh-huh.

Q. I'm sorry. Could you repeat that?

A. In one capacity, yes.

Q. And pharmacies have medications on hand so that they can fill prescriptions when patients present them; correct?

A. That is their role.

Q. So if doctors are writing more prescriptions for a particular medication, you would agree that the pharmacy would place more orders for that medication from their distributor; correct?

A. If they have -- yes, if they need more medication, they

would place more orders for the said medication.

Q. Are you aware of any -- strike that. Dr. Waller, you're aware that the Government, acting through the Drug Enforcement Administration, decides how much of each opioid medication can be made each year, correct, in the United States?

A. I don't really understand the full mechanism of how that's done or who ultimately comes up with the number, how that's done. That's not something I was asked to write about.

Q. Okay. But you're aware that DEA -- have you heard it referred to as the quota, the DEA sets a quota for how much of each opioid medication can be produced in the United States each year?

A. I've heard that but I, I honestly wouldn't be able to expand on anything past that.

Q. Okay. Do you know anything about -- are you aware that DEA is required by law to set the quota at the amount needed to provide for the estimated medical, scientific research, and industrial needs of the United States?

MR. FARRELL: Objection, Your Honor, outside the scope of direct, lack of foundation.

THE COURT: Overruled.

THE WITNESS: I don't know.

THE COURT: I think latitude should be permitted

here and I think this is proper. So, go ahead, Ms. Wicht.

MS. WICHT: Thank you, Your Honor.

BY MS. WICHT:

Q. I think you said your answer was you don't know?

A. No. That's not an area of my expertise.

Q. Okay. Are you aware that DEA increased the quota for prescription opioids that could be made by manufacturers almost every year from 1993 through 2013? Are you aware of of that?

A. No.

Q. Dr. Waller, you were qualified this morning as an expert in -- I'm trying to find my notes. I'm sorry. Well, one of them was addiction; correct?

A. That is correct.

Q. Thank you. And -- okay. So I want to turn to ask you -- one of the, one of the bases -- one of the things that you cited when you were talking about your background and your expertise with Mr. Farrell was your participation in the American Society of Addiction Medicine; correct?

A. That is correct.

Q. Okay. And I believe you said that you have held -- you spend most of your time with that professional organization versus something more general like the AMA; correct?

A. That and American College of Emergency Physicians I do some work for. You're correct. American Society of

Addiction Medicine is where I spend the vast majority of my time.

Q. Okay. And you testified this morning that you were an editor and an author for publications put out by the American Society of Addiction Medicine; correct?

A. That is correct.

Q. Okay. I want to ask you some about those, about your publications.

Now, Dr. Waller, you have previously described a sea change in opioid medication utilization and supply that began in the mid 1990s or so; correct?

A. At some point.

Q. Okay.

A. I'm not sure which specific documentation.

Q. Okay. That, that -- I'll represent to you that's taken from your report in this case, Dr. Waller.

A. Okay. It was written a bunch of months ago.

Q. But it's your opinion that that sea change hit its peak between 2010 and 2012; correct?

A. Correct.

Q. Okay. So I want to talk about, I want to talk about that for a moment, sort of unpack your observations of that based on your professional experience.

A. Uh-huh.

Q. So you attended medical school from 1999 until 2003;

correct?

A. That is correct.

Q. And in medical school you were taught that the utilization of opioid medications in acute traumatic pain and palliative care can be very effective; correct?

A. Not to that extent.

Q. Not to that extent?

A. We received very little training in medical school about the utilization of opioids past dosing and pharmacology.

Q. Okay. And at the time that you were in medical school, you characterized the use of prescription opioid medications in patients with chronic pain as a gray area. That is to say, different medical professionals have different opinions. Correct?

A. Correct.

Q. Now, your residency -- after medical school, you went on to your residency; correct?

A. Yes.

Q. And that was 2003 to 2006?

A. That is correct.

Q. Okay. Now, by the time you entered your residency, the practice of pain as the fifth vital sign was being implemented in hospitals; correct?

A. Correct.

Q. And pain as a fifth vital sign was the practice of monitoring patient pain as closely as other vital signs like blood pressure and respiration; correct?

A. Correct.

Q. It was not only monitoring patient pain, but also treating that pain more aggressively, relieving pain; correct?

A. Correct, not necessarily relieving but addressing.

Q. Addressing pain, okay. And that concept, pain as a fifth vital sign, came from the Joint Commission on Accreditation of Healthcare Organizations. Is that correct?

A. That is correct.

Q. And that organization, just for ease of reference, is frequently called by the acronym JCAHO or just the Joint Commission; is that correct?

A. Joint Commission is the current term.

Q. Joint Commission. Thank you. So what is the Joint Commission? What does it do?

A. It's not an area of expertise, but it's known to be the regulatory body that the Government uses to identify and evaluate hospitals for safety.

Q. And in order for a hospital to participate in federal healthcare programs like Medicaid and Medicare and things like that, the hospital must be accredited by JCAHO. Is that your understanding?

A. That is correct.

Q. Okay. And the Joint Commission made implementing pain as the fifth vital sign a criteria for accreditation in that early to mid 2000 time frame, didn't it?

A. Yes.

Q. So hospitals and the doctors who were operating in those hospitals had to comply with that requirement; correct?

A. Correct.

Q. And you would agree, wouldn't you, that pain -- the practice of pain as a fifth vital sign had an effect on physician prescribing practices with respect to opioids; correct?

A. For some.

Q. For some physicians?

A. Uh-huh.

Q. Okay. Are you aware that the City of Huntington has sued the Joint Commission alleging that the Joint Commission's promotion of pain as a fifth vital sign caused the opioid epidemic?

A. I was not.

Q. Okay. I'd like to show you some of the allegations from that complaint and just ask you about them.

If I could have slide 5, please.

This is from the complaint filed by the City of

Huntington against JCAHO. And you can see hopefully on your screen that the city alleged that JCAHO teamed with Purdue Pharma and grossly misrepresented the addictive qualities of opioids and fostered dangerous pain control practices.

Do you agree with what the city has alleged there?

A. It's not an area that I've dug deeply into, but enough to know that I've seen newspaper articles and, you know, a couple of reports that have talked about the underestimation of risks with opioids and overestimation of utilization of pain.

Q. And that link those things, at least in part, to the Joint Commission and their accreditation standards; correct?

A. I haven't really seen it linked directly to Joint Commission because the people that developed the pain as a fifth vital sign were people from the American Pain Society and other national organizations that came together to do that from a group. And I remember that piece only because we had somebody give us a lecture on it in residency, you know, about how it got there.

Q. About how pain as a fifth vital sign came to be developed?

A. The concept behind it and the idea of having it.

Q. Okay. Okay. Well, let me --

Can I have slide 6, please?

I guess I'll say irrespective of how pain as a fifth

vital sign came to be developed, do you agree with the City of Huntington's allegation that JCAHO zealously enforced those standards through its certification program?

A. I don't know if I can speak to the danger of the enforcement of that. I think they did enforce it. But, I mean, I have a hard time -- I haven't read this. I don't know about this. I mean, so pulling out single sentences out of context are going to be really tough for me to apply it to so --

Q. Okay. But you would agree that JCAHO did enforce the pain as the fifth vital sign standard --

A. Sure.

Q. -- in the accreditation process?

A. Yeah, it was one of their points of accreditation.

Q. Okay.

If I could have slide 8, please.

The City of Huntington alleged that JCAHO conducted a series of educational programs, and that those educational programs were devoted in part to correcting clinicians' misconceptions about pain treatments, including an exaggerated fear of addiction resulting from use of opioids.

Do you agree with that allegation by the City of Huntington?

A. I don't have the data -- I mean, I can only speak to my own experience and that's not really a larger contextual

experience because while this was going on, I was practicing, you know, medicine and hadn't really -- I wasn't even in the addiction space as these things were going on. I was just learning to not hurt people in the ER.

Q. Okay.

A. But, but I think --

Q. So to the extent these educational -- these educational programs exist, you simply weren't -- you didn't receive them, so you just don't know either way; correct?

A. Correct.

Q. Okay.

A. I've received a lot of education, but I'm not sure if any of these would really fit specific to this.

Q. Okay.

May I have slide 9, please?

The City of Huntington alleged that while JCAHO's pain management standards never overtly required opioid treatments, the expectation that every patient, no matter how presented, should be asked about pain vastly expanded the market for opioid treatments.

Do you agree with that allegation by the City of Huntington?

A. I just want to read through it.

Q. Sure. Take your time.

(Pause)

A. I think, again, just because, you know, it's out of context, I think the statement about vastly expanded the markets for opioid treatments I think for some physicians, they chose that as their modality of treatment for pain.

Q. So for some physicians it is true that the JCAHO pain management standards increased their prescribing of opioid medications; correct?

A. I can't speak for the entirety of like physicians but, you know, I would say that -- I would assume that some did that.

Q. And it's fair to say that the general gestalt in the medical community at the time of your residency, given the focus on pain as a fifth vital sign, was that opioid medications were the go-to option for the treatment of chronic, non-cancer pain; correct?

A. I wouldn't say that's how I was taught. I mean, I worked in an interstate hospital where we saw a lot of acute pain, gunshot wounds, stab wounds, you know.

So in my training, I would say that I had very little interaction with people with chronic pain as they would be pushed to other parts of the system.

Q. So is it your testimony today that it was not the general gestalt at the time, given that pain as a fifth vital sign was being implemented in hospitals, that the only lever to pull for the treatment of pain was prescription

opioids?

A. Not while I was training.

Q. Okay. Do you recall providing a deposition in this matter, Dr. Waller?

A. I do.

Q. Okay. Was that about August 3rd, 2020? Does that sound right?

A. Seems correct.

Q. And you were under oath at the time of the deposition; correct?

A. I was.

Q. And you told the truth in your deposition I'm sure; correct.

A. To the best of my ability, yes, for all six and a half hours.

Q. Okay. Oh, I'm sorry.

MS. WICHT: I'm going to ask if Dr. Waller's deposition transcript could be passed out. And we have three copies to hand to the Court and the staff --

THE COURT: Okay.

MS. WICHT: -- and a copy for the witness and a copies for all the parties.

BY MS. WICHT:

Q. And, Doctor, do you have the transcript in front of you?

A. I do.

Q. And I'll ask you -- I'm going to play the clip for you, but I'll ask you to turn to Page 56 and you're welcome to follow along. And I'm going to play a clip from Page 56, lines 8 through 18. And if you could play clip 8, please.

(Video deposition played as follows:)

"Q. Okay. Just to clarify, is it your understanding that as of 2003 to 2006, a portion of the medical field felt that opioids were safe and effective for the treatment of chronic pain?"

"A. I can't speak for everybody, but it was the general gestalt at the time given that pain as the fifth vital sign was being implemented in hospitals and as such that it was felt that that was the only lever we had to pull for the treatment of pain for those that didn't do a deeper dive, yeah."

BY MS. WICHT:

Q. Was that the testimony that you provided in your deposition, Dr. Waller?

A. It is.

Q. And doctors who were prescribing opioid medications for chronic non-cancer pain at this point in time -- at that point in time?

A. Uh-huh.

Q. Sorry. You have no reason to believe that those

doctors were not acting in good faith in the practice of medicine; correct?

A. No. I felt like as chief resident, some were lazy. But that was, that was the point that I had made on that one. But it wasn't the gestalt at my location. It was the gestalt as I had stated there. So both were the same.

Q. And just to clarify, because I think when I asked the question and you answered "no," I think the record might be a little bit unclear.

So you have no reason to believe that doctors who were prescribing opioid medications for chronic non-cancer pain at that time were not acting in good faith; correct?

I just put a lot of negatives in there. I'm sorry. Why don't we strike that and try it again.

Okay. Doctors who were prescribing opioid medications for chronic non-cancer pain in the mid 2000s, you have no reason to believe that they were not operating in the good faith practice of medicine; correct?

A. To remove the negative and return to positive, I believe that they were acting in good faith.

Q. Thank you. You improved that and I appreciate it.

I want to ask you about a book authored by Dr. Scott Fishman titled *Responsible Opioid Prescribing.* Are you familiar with that book?

A. I am.

Q. Do you know that that was published in approximately 2007, so just shortly after you finished your residency?

A. It was.

Q. And did that book purport to describe, as its title suggests, methods for doctors to engage in responsible prescribing of prescription opioids?

A. I don't remember -- I don't recall the specifics of the book. I read it I think back at that time because it was distributed in the State of Michigan where I was practicing.

Q. And was it -- when you say it was distributed in the State of Michigan, you mean that the Board of Medicine in the State of Michigan distributed it out to every doctor in the State of Michigan? Is that correct?

A. Made a copy available, yes. I don't know who did it. I assume -- you know, I'll take your word for it being some body other than myself purchased it.

Q. Some regulatory body made a copy available to every --

A. Someone said, "You have to read this," which is not uncommon in medical school, residency, or reality.

Q. You get publications thrust upon you that you're required to read?

A. Yes.

Q. Are you familiar with what the plaintiffs in this case have said about Dr. Fishman's book in their complaint?

A. Not specifically, no.

Q. Okay. I'm going to show you some of that and ask you if you agree with it.

Could I please have slide 20?

Okay. So in this case plaintiffs have alleged that Dr. Fishman authored a physician's guide titled *Responsible Opioid Prescribing* which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

Do you agree with that? Is that consistent with your recollection of the book?

A. It's consistent with -- I believe that this was the core reason that I got into a very loud argument with my chief of our department because I felt like this book was inappropriate.

Q. You didn't, you didn't agree with Dr. Fishman's book?

A. I didn't. It did not comport with how I was taught where I was trained.

Q. Okay. And still on the next paragraph, do you recall that Dr. Fishman emphasized the catastrophic under-treatment of pain and the crisis such under-treatment created?

A. I don't recall enough about the book, to be honest, to be able to answer that from a -- I'm digging into my hippocampus and I'm not finding an answer.

Q. Okay. But it's your view, I believe you said, that the, the book by Dr. Fishman was wrong in nearly every way;

correct?

A. Well, in, in concepts that were being pushed. I don't know if in every way. But specifically to the utilization of opioids for chronic pain management, yeah.

Q. You didn't agree with the concept that he was advocating for opioid treatment as a viable and safe option to treat chronic pain; correct?

A. That concept I did not and do not agree with.

Q. Okay. What is -- are you familiar with the Federation of State Medical Boards?

A. I am.

Q. Okay. And what is that generally?

A. Generally, it's the regulatory body that oversees the licensed physicians and other practitioners within the state.

Q. Okay. Well, I'm asking you now about the Federation of State Medical Boards, sort of the umbrella -- each state has its own medical board; correct?

A. Correct.

Q. And then do you understand that there's a Federation of State Medical Boards that's sort of an umbrella organization over those?

A. Correct. I'm sorry. I didn't hear the Federation part.

Q. No problem, no problem. That is sometimes referred

to -- frequently referred to as the FSMB?

A. Yes.

Q. Okay. Are you aware that the FSMB published guidelines for the use of controlled substances for the treatment of pain?

A. I am.

Q. Generally?

A. Generally.

Q. And are you aware that the first set of those were published in 1998 or thereabouts?

A. Not of that. I was not involved in the medical arena at that point.

Q. Too early for your time?

A. I had a lot of chemistry going on at that point.

Q. Okay. Are you familiar with what plaintiffs in this lawsuit say about the FSMB guidelines?

A. Not specifically.

Q. Okay. I'm going to show you some of that and ask your opinion about it.

Could I have slide 22, please.

The plaintiffs have alleged in this case that the 1998 FSMB guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were essential for the treatment of chronic pain,

including as a first prescription option.

Are you -- do you agree with that allegation? Are you familiar with that?

A. I never read the 1998 guidelines.

Q. Do you recall if you -- the FSMB guidelines were updated from time to time. Do you understand that?

A. I do. I've never read or utilized those.

Q. Okay. Are you aware that DEA endorsed the FSMB guidelines for the use of controlled substances in the treatment of pain?

A. No, I'm not aware of that.

Q. Not aware one way or the other?

A. No.

Q. Okay. I want to turn to your role as an author and editor in the American Society of Addition Medicine that you referred to earlier today.

Just a little bit of background. The American Society of Addiction Medicine was founded quite some time ago. It was founded in the 1950s or so. Does that sound right to you?

A. By Ruth Fox, correct.

Q. And is the membership of the -- do you refer to it as ASAM? How do you refer to it?

A. It's ASAM.

Q. ASAM?

A. Yeah.

Q. Is the membership of ASAM mainly composed of clinicians?

A. Varying professional designations. We have physicians, PAs, nurse practitioners. We have licensed clinical social workers, licensed psychologists.

Q. And you're a member of ASAM; correct?

A. I am.

Q. And you've worked with them in a number of capacities over the years; correct?

A. That is correct.

Q. And including -- well, the ASAM published a handbook on pain and addiction; correct?

A. That is correct.

Q. And you were both a co-author and an editor of that handbook; correct?

A. One of the sub-editors, yes.

Q. Okay. And I believe you mentioned that this morning with Mr. Farrell when you were talking about your expertise in the subject matter; correct?

A. Correct.

Q. Okay. So I would like to provide you with -- I'm going to ask to provide you with what's been marked for identification purposes as defendants' -- DEF-WV-03123.

Okay. Do you have that in front of you, Dr. Waller?

A. Yes.

Q. Okay. And this is not the whole book, obviously, but do you recognize that as the cover page and title page and introduction of the handbook?

A. Yes, ma'am.

Q. And we see your name there on the front listed as one of the editors; correct?

A. Correct.

Q. Now, the purpose of this handbook was to provide general guidance to doctors on how to treat patients who have both identifiable chronic pain and concurrent addiction; correct?

A. Correct.

Q. And when was the handbook published?

A. I don't know the exact date, a few years ago.

Q. Around 2018? Does that sound correct?

A. That sounds right.

Q. And the handbook is available for sale today on the ASAM -- through the ASAM website; is that correct?

A. I would assume so, yes.

Q. And Amazon and other places as well. And I will represent to you that if you go to the ASAM website where the book is available for sale, they describe it as -- they say that it is intended to be an invaluable evidence-based tool for clinicians to manage the complex relationship

between pain and addiction. Would you agree with that?

A. Not really.

Q. You would not agree with that?

A. That seems communication-y to me. It wasn't written by somebody who worked on this, on this book.

Q. What would you, what would you -- do you agree that the book is intended to be an evidence-based tool for physicians?

A. It was intended to elucidate some areas of difficulty in understanding. You know, to be honest with this book, it was, it was interesting because all of us were doing this as volunteers, as you normally do in these societies. And it took us almost two years to get it completed and really only because Bonnie Wilford took it over and finished it.

So my role in this book is probably overstated just with my name and editorial page to be bluntly honest. I wrote my chapter and answered some questions for Bonnie. And she was, rest her soul, kind enough to put me on as an editor.

So if I'm going to be just brutally honest about my role in this book, that would be the totality of my role. It was pretty much my chapter in helping answer a few questions, but I would have to give credit for pulling it together and publishing it to Bonnie.

Q. Well, you're identified as an author of the book,

though, correct, on the cover?

A. As an editor on the cover and then I did write one chapter in the book, yes.

Q. Okay. And now if we turn the page, you're identified as an editor on the title page as well; correct?

A. Correct.

Q. And you -- when you were describing your expertise this morning with Mr. Farrell, I think you listed this handbook as one of the pieces of supporting evidence for your expertise in this area; correct?

A. The chapter that I wrote for sure, yes.

Q. And pardon me if I'm repeating this, but I think you agreed that the intent of the book is to be an evidence-based tool for clinicians; correct?

A. I would say there are chapters within this book that were really intended to be a systematic review and an evidence-based chapter. Some of them, upon my post-reading, were more opinion pieces from doctors than evidence-based if I was -- I mean, I'm sitting in a place of truth, so I might as well be truth-y.

Q. Okay. So it's your testimony today that the American Society of Addiction Medicine of which you are a member is selling a handbook of which you are a co-author and a co-editor, and that ASAM puts forward as an evidence-based tool for clinicians managing pain and addiction and it's

your testimony today that some of the book is, in fact, not that? Am I understanding you correctly?

A. No. It is the evidence-based opinion of some. Areas in which there are not enough evidence to make substantive in-roads, they did their best to come up with opinions on those from an expert standpoint.

So they didn't fabricate anything. There was nothing that was, you know, unwillfully put. But what happened was as people sometimes when they write chapters fill in the gaps with their experience when there's no data to back that up. And I think that some people's experiences differ.

So there were a few chapters in this book specifically that my experience differed greatly from. And, so, my opinion would differ greatly.

But the evidence that they cited is true evidence and the stuff that they use. So I think that there are some, some chapters that there were a large amount of evidence. So it became pretty easy to do a systematic review. And this is the first book of its kind to come out, you know. It really tries to combine those two very complex efforts.

So I felt like for a first effort it was, it was a good first effort. And on the second effort we made changes to make sure that those things that need to be systematically and differentially evaluated are done so.

Q. Okay. And there's not a -- this is the current edition

of the handbook; correct? There's not a second edition?

A. That's correct.

Q. Well, maybe as we go through a few things you can help identify those different categories for me.

A. Sure.

Q. Okay. So what you have in front of you is the handbook's introduction which was written by Dr. Ilene Robeck. Do you see that?

A. I do.

Q. And you're familiar with Dr. Robeck; correct?

A. I am.

Q. And you worked with her in the course of editing the handbook?

A. Yes.

Q. And in your interactions with Dr. Robeck, you didn't have any reason to question her good faith or her medical judgment, did you?

A. Neither of those were questioned, no.

Q. And in your opinion, Dr. Robeck is a good physician?

A. I've never reviewed her interaction with patients. She works with the V.A. Hospital and works really hard to help those patients.

Q. Okay, okay. If you'll turn to the first paragraph of the introduction.

And if I could have slide 13, please.

The first paragraph of the introduction says, "Our understanding of pain and addiction have evolved dramatically over the past decades, leading to significant changes in the treatment of both medical disorders. Perhaps none have been more dramatic than the revolution in attitudes towards the use of opioid analgesics for pain."

Do you agree with that statement by Dr. Robeck?

A. Yeah, with minor caveats, but overall, yes.

Q. Okay. And Dr. Robeck goes on to say --

If I could have slide 14, please.

"Ten years ago, responsible scientists and clinicians focused on the problem of inadequate diagnosis and management of pain. To address this very real problem, they led a movement to promote wider and more intensive use of opioid analgesics."

Do you agree with Dr. Robeck's statement that 10 years ago responsible scientists and clinicians focused on the problem of inadequate diagnosis and treatment of pain?

A. I agree that that's her opinion.

Q. That's not your opinion?

A. I don't know the clinicians of which she speaks. I don't know the responsibility portion for each of those. And she and I differ on opinions around this space from an academic standpoint in a number of areas.

Q. Okay. But you have no reason to question that this

represents her good faith opinion, correct, what she's written?

A. No. This is, you know, her good faith opinion, yes.

Q. Okay, okay. I'm sorry. I'm going to hand out one more thing. I'd like to hand you another segment of the book. I'm going to hand you what's been marked for identification purposes as DEF-WV-03125.

Okay. And if I could have slide 15, please.

So, Dr. Waller, this is Chapter 9 of the ASAM handbook on pain and addiction. Correct?

A. Appears so, yes.

Q. And it's titled "Understanding and Preventing Opioid Misuse and Abuse." Correct?

A. Correct.

Q. Now, the format of the ASAM handbook is that at the end of each chapter, there are suggestions for further reading on the topics discussed; correct?

A. For which portion? I'm sorry.

Q. At the end of each chapter.

A. Oh, at the end of each chapter. I'm sorry. Yes.

Q. Okay. And there are resources for more information on the topic discussed in that chapter; correct?

A. Correct.

Q. Okay. In fact, if you flip to the end of 03125 that's in front of you, the end of Chapter 9, you'll see actually

on the second to last page there you'll see "for more information on the topics discussed." Correct?

A. Uh-huh.

Q. And that's on the slide -- if I could have slide 18, please.

And you see listed as more information on the topics discussed, among other things, you'll see Dr. Fishman's book, *Responsible Opioid Prescribing*." Correct?

A. I do see that.

Q. And the handbook says that, "This 150-page book by pain expert Scott Fishman, M.D., translates the FSMB's model policy on pain management into practical guidelines for office-based practice."

Do you see that?

A. I do see that.

Q. Now, that's the same book that plaintiffs allege here misled doctors about the risks of prescribing opioids and causing them to overprescribe opioids; correct?

A. That's correct.

Q. And the same book that you earlier expressed your disagreement with; correct?

A. Correct.

Q. So is it your testimony as you sit here today that as one of the editors of this handbook that the particular resources cited by the authors in Chapter 9 are not

materials on which physicians reasonably could rely?

A. I think the way that they -- well, first, if I had been the author, that wouldn't have been in there. I wasn't, however.

The -- however, the way that they talk about it is just an explanation of the FSMB's -- a further explanation of the FSMB's guidelines and not as a tool to rely on, but more just an explanation of those guidelines for practitioners.

Q. Well, they describe it as practical guidelines for office-based practice; correct?

A. Well, built on top of the FSMB guidelines. I mean, so basically they're describing it as a distillation of those. They're not describing it as you have to go here. They're just describing it as -- the FSMB has guidelines.

And, therefore, this is a book that further delineates those guidelines into the ability to apply it. I wouldn't state that they're holding it up with a gold star. I think they're just very specifically stating here that it's there.

Q. Well, they're pointing physicians -- or they're pointing clinicians who might read this book and want more information on the topic discussed, they're pointing them to Dr. Fishman's book; correct?

A. Yeah, as a resource to understand how to implement the FSMB guidelines.

Q. Did you, did you tell the authors of this chapter

before the handbook was published that, that you believed Dr. Fishman's book was unreliable?

A. I did not review this chapter.

Q. Okay. Let's look at who the authors were of Chapter 9. If we could go back to slide 15, please, we can see those.

Are you familiar with Dr. Robert DuPont?

A. I am.

Q. And he is the Distinguished Fellow of the American Society of Addiction Medicine; correct?

A. As I am, yes.

Q. Okay. Now, Ms. Wilford I believe you already talked about. She was one of your co-editors on the handbook?

A. She was the main editor of the handbook.

Q. And she served as the editor of multiple editions of multiple different ASAM publications; correct?

A. Yes.

Q. And, in fact, are you aware that she was presented with ASAM's President's Award for Lifetime Achievement in Addiction Education?

A. Absolutely.

Q. And Dr. Theodore Parran, now, he's certified in addiction medicine by ASAM; correct?

A. Well, from one of the original certification pieces. He's not ABMS Board Certified and hasn't seen a patient in 35, 40 years.

Q. Okay. He's a Professor at Case Western Reserve Medical School?

A. I'll take your word for that.

Q. Okay. You don't know. That's fine. And do you know if he's someone who practiced or practices in the field of addiction medicine?

A. I've never known him in the -- he's worked in administration since the Nixon administration.

Q. Okay. Do you know that Dr. Parran was retained by these same plaintiffs' counsel to testify in the Cleveland MDL opioid trial?

MR. FARRELL: Objection, Your Honor.

THE COURT: What's the basis?

MR. FARRELL: I don't like the question. It's not relevant.

THE COURT: Well, your objection is overruled, Mr. Farrell.

MR. FARRELL: Thank you.

THE COURT: Maybe you can ask a question he likes, Ms. Wicht.

MS. WICHT: I can keep trying, Your Honor.

THE WITNESS: I was not aware until yesterday and it was just mentioned, "Do you know this guy Ted Parran?"

BY MS. WICHT:

Q. He's been retained as an expert on the plaintiffs'

side in the opioid litigation; correct?
A. It was -- that wasn't the -- no, that wasn't the whole -- the conversation wasn't specifically -- it was more just a, "Hey, do you --"
Q. Okay. Well, did you -- when you were serving as the co-editor of this handbook, did you question the expertise of Drs. DuPont and Parran and Ms. Wilford to write on the subject of understanding and preventing opioid misuse and abuse?
A. I outwardly questioned Bob DuPont's capability to write this chapter.
Q. I'm sorry? Say that again.
A. I said I outwardly questioned in the early stages of Dr. DuPont's relevance in writing this chapter.
Q. Okay. And to whom did you raise those questions?
A. The editorial committee at a meeting that we had as we were going over authors.
Q. And I note that Dr. DuPont ended up as the author of the chapter; correct?
A. Shows the weight that one holds at certain stages in life.
Q. So I am going to infer that your views on that subject were not accepted by ASAM; correct?
A. By the editorial group there, correct.
Q. By the editorial group, okay. Now, since Dr. Parran

and his co-authors included Dr. Fishman's book on this list of, of more information on the topics discussed, there's no doubting that it was their judgment that Dr. Fishman's book was a reliable source to point doctors to; correct?

A. That would be my assumption as it's in the chapter.

Q. Okay. And they wouldn't have listed Dr. Fishman's book if they thought it was full of falsehoods; correct?

A. That would also be my assumption.

Q. Okay. I want to continue forward in time. I'm going to go back to Dr. Robeck's introduction to the handbook. Apologies for switching between documents here.

So if I could have slide 26 back, please, and if you could pull up the introduction.

Do you see that the next paragraph from the ones we've already read Dr. Robeck says that, "Over the past five years, clinicians, policymakers, and society as a whole have witnessed the adverse effects of this approach as evidenced by dramatic increases in the rates of opioid use disorder, overdose, and death, all accompanied by startling growth in the non-medical use of prescription opioids as well as consumption of illicit opiates such as heroin."

Now, do you agree in the five years before your handbook was published clinicians, policymakers, and society as a whole witnessed the adverse results of this approach to opioid medications?

A. Oh, I would definitely say we saw adverse approaches and the opioid medications were a part of it, yeah.

Q. And do you agree that that presented a dual challenge to health care professionals who wanted to prioritize treating pain but also had to consider that some individuals used opioids in a way that was dangerous?

A. Could you repeat that question for me?

Q. Sure. Do you agree with Dr. Robeck that there was a dual challenge presented to healthcare professionals who wanted to prioritize treating pain, but also had to consider that some individuals used opioids in a way that was dangerous?

A. I disagree with the way that it was stated in the sense that this was -- the question was not about whether or not to treat pain. It was whether or not to utilize opioids to treat pain.

So I disagree with the way that it's stated because it's kind of a false choice conundrum. It's like -- the way that she stated it is that you either use opioids or you don't treat pain, you know, from a logical framework standpoint.

I disagree with that because the treatment of pain doesn't require opioids the vast majority of the time. And, so, the way that that is stated, I don't, I don't agree with that.

Q. But you have no reason to believe that that was not -- you understand that to have been Dr. Robeck's good faith medical opinion; correct?

A. It's her intro, so it's my assumption, yes.

Q. Okay.

THE COURT: When you get to a stopping point, a convenient place, and you may be there now, we'll break for the lunch, take the lunch break, Ms. Wicht.

MS. WICHT: Actually, Your Honor, this would be a very good time.

THE COURT: This would be convenient?

MS. WICHT: Sure.

THE COURT: Okay. We'll come back at 2:00.

MR. RUBY: Judge, Your Honor, before we go, would there be a moment just to raise a quick point on the Gupta ruling that the Court made this morning?

THE COURT: Yeah, go ahead.

MR. RUBY: The, the point that we wanted to raise, Judge -- and we recognize that the Court in a bench trial, of course, has considerable flexibility to allow evidence to come in conditionally and then subsequently rule on the basis of the record, and understand that that's what the Court intends to do with Dr. Gupta.

The point that we wanted to make sure that, that the Court was aware of is that with respect to Dr. Gupta,

there's also an issue of disclosure in addition to the issue of admissibility.

So in the deposition that we took a little under three weeks ago, there were four studies that Dr. Gupta referenced on the subject of gateway theory and two studies that he referenced on the subject of Neonatal Abstinence Syndrome. And that was the first time that we had heard of those or heard that Dr. Gupta was relying on them.

We still don't have them. All we have are references to who the authors are. We don't have titles, dates, citations.

And, so, unlike the scenario where the Court can let the record come in and then subsequently decide on the basis of the record whether the evidence is admissible or not, on these opinions we don't have an opportunity to build our record because we don't have the studies that he's relying on.

And, so, our view, Your Honor, is that because of the failure of disclosure and our consequent inability to build the record, that the procedure that would normally make some sense in a bench trial to let the record come in and then decide afterward doesn't work for those opinions.

So we'd ask the Court to at least consider whether the opinions that are relying on these studies should be treated separately and excluded because of the disclosure violation

as opposed to the expert, non-expert distinction.

THE COURT: How much of his testimony does that impact?

MR. RUBY: It's gateway theory and NAS, Your Honor. And I don't know how much of that -- how much sort of in terms of the portion of what plaintiffs intend to do with him it impacts.

But it's, it's -- all I can say, Your Honor, is that it's a fundamental problem for us to try to examine him tomorrow on those opinions when we still don't have the studies that he himself said for the first time three weeks ago he's relying on.

THE COURT: Mr. Farrell, do you want to respond to that?

MR. FARRELL: Yes, Your Honor.

Part of this is probably my fault with all of this. So I want to take a little brief moment and explain to you the process of what happened here.

In West Virginia we knew that we have a lot of physicians and professionals in this community who have direct knowledge and have studied the evolution of the epidemic here. We, we knew they also had very strong opinions as to certain matters that would reflect some of our theories.

So do we hire them as experts? Do we talk to them

beforehand? Do we publish reports? We're reading all of these reports that Dr. Gupta has issued on behalf of the state, and we're trying to figure out how to get it in the record, how to give fair notice.

And to be fair to the plaintiffs, we have disclosed Dr. Gupta ages ago as a prominent witness in this case. So when he was deposed, he started -- they were eliciting on cross-examination a whole host of opinions.

Dr. Gupta will answer whatever question is asked of him based upon his personal experience in this role. This isn't like we grabbed somebody from California and asked him to come in and study what happened here. Dr. Gupta was here.

He's been now deposed twice. He has published extensively on what happened here. So the fault if it lies anywhere is on me for this non-retained expert business because what I said to my team was they're asking questions and I don't want them to object on his opinions that were not in the record.

So I asked the team to go and take a line item review of his entire deposition, and anything that they think could be an opinion, I want you to re-disclose. So this is my fault for having over-disclosed all of this.

That being said, there can be no doubt that most of this is elicited by them on cross during deposition.

THE COURT: You're not suggesting, Mr. Ruby, that

everything that he relied on as the basis of his opinion has to be disclosed, are you?

MR. RUBY: Your Honor, we would --

THE COURT: You don't have to be given copies of everything that he referred to that was the basis for his opinion, do you?

MR. RUBY: We would suggest that to the extent he's relying on outside studies, there's a difference, Your Honor. And this is why the non-retained versus retained business with Dr. Gupta has gotten complicated.

To the extent that he is relying on his own personal experience, then, you know, it's not our -- well, I'll just say that in light of the Court's ruling this morning, we're not going to take the position that, that Dr. Gupta's opinions he's going to testify to tomorrow or the facts which he would testify based on his personal experience, that there had to be some prior disclosure in detail of personal experience.

What did have to be disclosed beforehand is outside research, third-party studies that, that he's relying on that aren't, aren't his personal involvement with these issues or facts that he's personally observed.

To the extent he's giving opinion testimony that's based on third-party studies and outside research, we were entitled to -- because that takes him out of the bounds of

what a non-retained expert can properly testify to, we were entitled to be told to be, to get disclosure in advance of the studies on which he was relying just like we would with any other expert, and then to be able to read those studies themselves to in his deposition ask him the questions about those studies and his interpretation of them and how they informed the opinions that he was given, and then to use that discovery, that deposition testimony that he would have gotten from them to inform the examination of him that we're going to do tomorrow or Thursday.

And, so, I'm not asking the Court to throw out Dr. Gupta or say that Dr. Gupta can't come or even at this point to say that Dr. Gupta can't give non-retained opinion testimony because the Court has made clear that certainly at least on many of the subjects for which he would give non-retained opinion testimony, the Court is going to wait until the record is developed to decide if that's non-retained testimony in the sense that's allowed by the law or instead retained expert testimony that should be excluded.

The very narrow issue that we would like the Court to take another look at right now is whether the opinions that were based at least on part on studies, outside studies that were never disclosed to us, whether we can be forced to try to examine him tomorrow about those.

THE COURT: I'm going to cut this short. I'm going to take his testimony. You can object at the time and I'll be better informed about what the issue is at that time.

But it seems to me that, that this is not something that should cut out part of his testimony if it's otherwise admissible. But I'll give you a shot at keeping it out as he testifies, Mr. Ruby, and that's the best I can do.

MR. RUBY: Thank you, Your Honor.

THE COURT: We'll be in recess until 2:00.

(Recess taken at 12:08 p.m.)

THE COURT: You may resume the witness stand, Dr. Waller.

And you may proceed, Ms. Wicht.

MS. WICHT: Thank you, Your Honor. Speaking of a well-timed lunch break, I think I, myself, probably only have about five more minutes.

THE COURT: Okay.

BY MS. WICHT:

Q. Good afternoon, Dr. Waller.

A. Good afternoon.

Q. I hope you had a nice lunch.

A. I did.

Q. Dr. Waller, you testified this morning about the diagnostic criteria for Opioid Use Disorder. Do you recall

that?

A. Yes, ma'am.

Q. Okay. And those are -- what was summarized on the screen, those are clinical criteria for diagnosing OUD; is that correct?

A. Correct.

Q. Okay. And then you also testified about a definition of addiction put forward by the American Society of Addiction Medicine. Do you recall that?

A. I do.

Q. And I want to just understand sort of the interaction between those two things. So, my question is, if someone meets the criteria in the DSM for OUD, would you agree that that person then meets the definition of addiction?

A. Yes.

Q. Okay. Now, would you agree that there are multiple factors that bear on whether any individual will develop addiction?

A. Of course.

Q. And one of those factors, I guess sort of generically described, could be the brain chemistry of the individual; is that correct?

A. Structure, function of the brain, yes.

Q. Structure and function of the brain? Okay. And not all individuals will find all substances rewarding in the

same way; is that correct?

A. That is correct.

Q. Okay. So, there are some individuals who, because of the structure, or function, or chemistry of the brain may be more susceptible to addiction than others, correct?

A. Correct.

Q. Okay. So, and that's true with opioids, correct? There are individuals, some individuals, who experience opioids as more rewarding than the average person?

A. Correct.

Q. And another factor that can play into whether a person will develop addiction or not is genetics, correct?

A. It's unclear exactly what role, but the answer is yes.

Q. Okay. So, there is at least -- genetics plays at least some role in the -- in whether or not a person is likely to become addicted?

A. That is the prevailing theory with thin evidence, but connectedness is probably the best way to discuss it.

Q. Okay. And there are some studies, in fact, that say as much as 50% or more of the risk of addiction is dependent on genetics, correct?

A. There are studies that say that.

Q. Okay. And adverse childhood experiences or trauma are also correlated with a risk for addiction, correct?

A. In adolescents, definitely. In adults, it's unclear,

but the evidence leans toward probably.

Q. Okay.

A. It's not a clear yes or no for adults, but for adolescents.

Q. Okay. But there is some evidence to support it for adults, to support that adverse experiences or trauma can be correlated with risk of addiction in adults?

A. Can be additive to the risk.

Q. Okay. And I wanted to just show you again, if we can, Mr. Farrell had up on the screen the ASAM definition of addiction this morning.

MS. WICHT: Could we put that up again? Thank you.

BY MS. WICHT:

Q. And I just wanted to ask you, the ASAM definition says that addiction involves complex interactions among brain circuits, genetics, the environment, and an individual's life experiences. And I take it that you agree with that?

A. I do. I think that it needs to be understood where within the paradigm of the development of addiction each of those things impact the disease. Some of those impact the probability of someone becoming addicted to a substance and other of those things make it harder for them to be treated once they've already developed it, but do not directly impact the development of addiction. Does that make sense?

Q. Yes. Okay.

MS. WICHT: Okay. I don't have any further questions at this time, Your Honor. I would like to move into evidence the two book excerpts that we've marked, which are DEFWV-03123 and DEFWV-03125.

THE COURT: Is there any objection to that?

MR. FARRELL: None.

THE COURT: All right. Hearing no objection, they're admitted.

DEFENSE EXHIBITS DEFWV-03123 & DEFWV-03125 ADMITTED

MS. WICHT: Thank you.

Thank you very much, Dr. Waller.

THE WITNESS: Thank you.

THE COURT: Mr. Hester, I guess you're next.

MR. HESTER: I'm up, Your Honor. Thank you.

THE COURT: Okay.

MR. HESTER: Your Honor, we just need to get our tech person set up.

THE COURT: Okay.

MR. HESTER: Sorry, Your Honor. It takes us a few minutes to switch.

Chris, are you ready? Okay.

All right. I think we're connected, Your Honor.

Are you ready Chris?

CROSS EXAMINATION

BY MR. HESTER:

Q. Good afternoon, Dr. Waller. My name is Timothy Hester. I represent McKesson.

A. Good afternoon.

Q. Good to see you. I wanted to return first to the subject of changes in the medical community's view on pain treatment that -- as they evolved over time. That's where I wanted to begin, Dr. Waller.

So, let me first hand you a document.

MR. HESTER: May I approach, Your Honor?

THE COURT: Yes, you may.

MR. FARRELL: Your Honor, a point of -- I guess it's sort of an objection. More of a point of clarification. Are the defendants -- if the defendants are going to be permitted to double dip or triple dip on the same subject matter with the witness, I would like the opportunity for the plaintiffs to be able to at least double dip on witnesses.

THE COURT: Well, you can redirect. Doesn't that take care of it?

MR. FARRELL: Well, we've got two plaintiffs, the City and the County. I guess my point is --

THE COURT: Oh, okay.

MR. FARRELL: If they can triple dip, we should be at least allowed to double dip.

THE COURT: Well, does anybody have a problem with that?

MS. MAINIGI: Well, Your Honor, I think, by in large, we're trying to have a lead person focus on the questioning and then others, if they've got particular follow-up left over, then they would -- then they would do that follow-up and, certainly, we don't have an objection if they follow the same procedure.

THE COURT: Well, I think if you want to switch off on redirect, that that would be okay. I don't want to unduly lengthen this, but I think each defendant has the right to cross examine a witness, so --

MS. MAINIGI: We're trying to be pretty lean about it, Your Honor. We're trying to have a primary and then just follow up.

MR. HESTER: Thank you, Your Honor.

THE COURT: Well, does that mean you're going to be the primary on all of them?

MS. MAINIGI: No, Your Honor. Absolutely not.

MR. HESTER: We'll have different primaries for different witnesses, Your Honor.

THE COURT: I thought that was a clever move on your part.

BY MR. HESTER:

Q. All right. Dr. Waller, I've handed you a document,

McKesson Exhibit 1135, an excerpt out The New England Journal of Medicine. Have you seen that before, Dr. Waller?

A. Not this particular article.

Q. Do you know this is an article published in The New England Journal written by Dr. Marcia Angell?

A. I can -- I see that as the author.

Q. Okay. You've not seen it before?

A. I was ten when it was published, so no.

Q. And you've not read it since even though you've been qualified as an expert in pain treatment?

A. I have -- I have not read an opinion piece, this specific one.

Q. Okay. Are you -- and you've not read this document?

A. Not to my knowledge.

Q. Okay.

A. I just did after you handed it to me. So --

Q. All right. Are you familiar with The New England Journal of Medicine?

A. I am.

Q. And are you familiar with Dr. Marcia Angell?

A. Not past -- hearing the name, never been in -- like, as far as I can recall, I haven't been directly involved with this person.

Q. Are you aware that the New England Journal of Medicine is influential in shaping medical opinion?

A. In times. Certain -- I should be specific on that. Certain specialties.

Q. And The New England Journal is a highly regarded source of information on the medical profession; is that right?

A. I would agree with that.

Q. And it's widely read by doctors across the country; is that correct?

A. Generally speaking, yes.

Q. And you can see on this -- on the second page of this document, if you look at the numbers at the bottom, it's .2 at the bottom. Do you see that Dr. Angell, at the time, was the Deputy Editor of The New England Journal?

A. I see that.

Q. And I may have asked you this. Did you know that she later became the Editor of the New England Journal of Medicine?

A. Unaware of that fact.

Q. In 1982, when this document was written, was it fair to say that the prescribing of opioids was at much lower levels than it was in later years?

A. Without knowing the exact numbers -- I'm sorry. Can you repeat the question? I was reading.

Q. Well, is it fair to say in the early 1980s when this article was published that the prescribing of opioids in this country was at lower levels than it was later, for

instance, in the 1990s?

A. I haven't specifically compared the two years, but based upon population and, you know, changes that I am aware of, it seems probable.

Q. Let me point you, if I could, to the second page of this document. The essay is headed "The Quality of Mercy". Do you see that?

A. I do see that.

Q. And do you see the second sentence of this essay? It says, "The treatment of severe pain in hospitalized patients is regularly and systematically inadequate"? Do you see that?

A. I do see that.

Q. Were you aware that Dr. Angell had said this in the New England Journal of Medicine around this time?

A. I was not.

Q. And let me ask you to look further down in that same paragraph. It stated, "It is generally agreed that most pain, no matter how severe, can be effectively relieved by narcotic analgesics." Do you see that?

A. I do see that.

Q. And were you aware that Dr. Angell had said this in the New England Journal of Medicine in 1982?

A. I was not.

Q. Let me ask you to look at the very end of this essay

over onto the third page. There's a statement at the end of the final paragraph. It reads, "Pain is soul destroying. No patient should have to endure intense pain unnecessarily. The quality of mercy is essential to the practice of medicine; here, of all places, it should not be strained." Do you see that?

A. I do see that.

Q. And were you aware that Dr. Angell had said that in the New England Journal of Medicine at this time?

A. No, I was not.

Q. Were you aware generally that there was a -- an evolving view in the early 1980s that greater attention should be paid to the treatment of pain in medicine in this country?

A. I cannot say that that was a focus of my attention at that point in time.

Q. Well, you're an expert in pain treatment, correct?

A. Not history.

Q. So, you're not aware one way or the other?

A. I'm aware of things I have been told by people who have consolidated information but I, again, was ten.

Q. Do you understand this essay to reflect the beginning of an evolving thinking about placing greater focus on pain as a factor that should be focused on in medicine?

A. I don't know if I can really comment on that. It's not

a systemic review. It's an opinion piece with a few references by a person who I've never met, don't know anything about, have no idea of their qualifications other than being an editor.

I don't know if they're a pain doctor, an addiction doctor. I don't know if they're a family doctor. I have no unearthly idea what Dr. Angell's professional knowledge actually is and how it reflects into this piece.

Q. You were -- you are aware generally that there was a re-thinking of focus on pain in the treatment in medicine during the 1980s and 1990s?

A. Only in a reflective sense of that conversation took place during medical school.

Q. Dr. Waller, you're a practicing physician in Michigan, correct?

A. That is correct.

Q. And you're licensed by the Michigan Board of Medicine; is that correct?

A. That's correct.

Q. And State Boards of Medicine play an important regulatory role for the practice of medicine; is that correct?

A. They do.

Q. And State Boards are responsible for keeping doctors up to date on developments in medicine; is that correct?

A. I would say that's less their role.
Q. That's one of their roles?
A. I don't even know if that's truly one of their roles.
Q. Well, do State Boards of Medicine from time to time provide doctors with information about standards of medical care?
A. I don't know if the State Boards of Medical Care do. It seems like the FSMB did with the one document that I was presented with earlier from 1999, if I'm not mistaken on the date.
Q. Are you aware that State Boards from time to time issue materials to doctors in their state apprising them of information on medical care and evolving standards of care?
A. I can think of one instance where I know for sure that that was the case that we discussed earlier, which was when they had -- I believe it was them in Michigan who had purchased the -- the book.
Q. So, you are aware that from time to time State Boards of Medicine do this, they provide information to doctors in their state about evolving standards of care?
A. I'm aware that that is something that they have the capability to do. I can't say that I follow it, just to be honest.
Q. And is one way that State Boards of Medicine communicate with doctors is through issuing a policy

statement on standards of care and developments in medical practice? Is that one way they do this?

A. I can't say that I've utilized one of their policy statements in my work.

Q. Are you aware that the West Virginia Board of Medicine plays a regulatory and oversight role for doctors in the State of West Virginia?

A. I would assume they have a Medical Board that does such a task.

Q. And that would include doctors who were maintaining their practices in Cabell County and Huntington; is that right?

A. I would assume so.

Q. Okay. Let me show you a document.

MR. HESTER: May I approach, Your Honor?

THE COURT: Yes, you may.

BY MR. HESTER:

Q. Dr. Waller, I've handed you a McKesson document, McKesson Exhibit 1219, a document issued or headed by the State of West Virginia Board of Medicine. You see this is a Position Statement on the Use of Opioids For the Treatment of Chronic Non-Malignant Pain?

A. I see that as the title.

Q. Yes. Have you seen this Position Statement before?

A. No, I have not.

Q. You weren't aware of it when you were opining in this case?

A. It had been mentioned to me, but I had not read it in its entirety.

Q. But it had been mentioned that there was this policy statement issued in 1997?

A. I'm not aware that the date was specified with it, but it -- that was the entirety of my knowledge, is it was mentioned to me that West Virginia's Medical Board had issued a statement. I had, however, not read that statement as, again, that was a number of years ago.

Q. So, this is an example of a policy statement that's issued by a State Board of Medicine to apprise doctors on a policy or a standard of care in the state, correct?

A. Well, I would have -- may I read it?

Q. Sure.

Q. Is this it in its entirety, front and back?

A. Yes, it is.

Q. And if it helps, I'm just going to focus on the first page.

A. Okay. Almost there.

THE COURT: Is there a date on this anywhere, Mr. Hester?

MR. HESTER: Yes, Your Honor. At the bottom of the second page, it's dated July 14, 1997, right at the

bottom.

THE COURT: Oh, okay. I see now.

THE WITNESS: Sorry. Since the first page refers to the second page, I need to read the second page to answer the question.

MR. NESTER: Sure. I'm with you.

BY MR. NESTER:

Q. So, my question is, this is a policy statement issued by the State Board of Medicine to apprise doctors in the State of West Virginia on a policy position of the Board at this time, correct?

A. My interpretation is that this is to let them know what their position on enforcement would be pertaining to this issue.

Q. Well, and in particular, if you look at the second paragraph, it says in the first sentence, "The purpose of this statement is to clarify the Board of Medicine's position on the appropriate use of opioids for patients with chronic non-malignant pain." Do you see that?

A. I see that. I don't think they've accomplished that, but -- at least on my reading, but I see that, yes.

Q. But the Board stated that that was the purpose for which it was issuing the policy statement, correct?

A. That is what is stated on the paper, yes, sir.

Q. Yes.

MR. HESTER: And, Your Honor, I would move McKesson Exhibit 1219 into evidence.

THE COURT: Is there any objection?

MR. FARRELL: Yes, Your Honor, there is. There's a lack of foundation from a witness with knowledge. I believe this witness had to actually read the document to understand what it was.

MR. HESTER: Well, Your Honor, my position would be that the witness is familiar generally with the practice of how State Boards of Medicine interact with doctors in state, as he testified, and that's sufficient foundation to bring this document in. The witness also indicated he'd been told about this.

THE COURT: Well, if I understood the witness, he testified that he knew about this; is that -- is that correct?

THE WITNESS: I knew that something had been written, but I didn't really know what it specifically stated or pertained to and had never read it.

THE COURT: Well, and it comes in just to show what the -- it's not hearsay, is it?

MR. HESTER: No.

THE COURT: It just comes in to show what their position was.

MR. HESTER: Right. Your Honor, we're not

admitting it for the truth.

THE COURT: I think I'm going to admit it. I believe Dr. Waller is a little weak as a sponsoring witness, but I think the fact that -- I think what he said qualifies it and I will admit it. The objection is overruled.

MCKESSON DEFENSE EXHIBIT 1219 ADMITTED

BY MR. HESTER:

Q. And, Dr. Waller, we discussed before that this document is dated in July, 1997; is that right?

A. That is the date on the document, yes.

Q. Right. And so, by 1997, there was greater emphasis being placed on the importance of pain treatment in medical practice; is that right?

A. I don't know if this document actually states that. This is -- I mean, honestly --

Q. I wasn't asking you about what this document said. I was asking you generally, in 1997, at that time, was there greater emphasis being placed on the treatment of pain in the medical profession?

A. I don't know if I can comment on that given I wasn't in the medical profession as of yet. I mean, I was still in graduate school at that point.

Q. You don't know even though you're a pain expert?

A. I'm an expert on how to treat pain in a patient sitting in front of me, yes, sir.

Q. All right. And were you aware that by the late 1990s, there was a greater emphasis on using opioids to treat pain?

A. As mentioned in some lectures that I had had, again, going through medical school and residency, but not as an experiential moment.

Q. And did you know that the Board of Medicine in this policy statement had stated that the Board recognizes that opioids are appropriate treatment for chronic non-malignant pain in selective patients? Were you aware that the Board of Medicine had issued that guidance to the doctors of West Virginia?

A. I think that's not the -- that single statement is not the totality of the advice given the way that I had read it. I agree that sentence is in there, but it's qualified by the preceding sentence, which is more specific.

Q. No, but I wanted to ask you about the sentence I wanted to point you to. And my question is, were you aware that the Board of Medicine had told the doctors of West Virginia that the Board recognizes that opioids are appropriate treatment for chronic non-malignant pain in selective patients? Were you aware of that?

A. No, I was not aware of that for all the reasons stated earlier.

Q. And if you go to the fourth paragraph, did you know that the Board had told the doctors of West Virginia in 1997

that a doctor need not fear disciplinary action by the Board if complete documentation of prescribing of opioids in chronic non-malignant pain, even in large doses, is contained in medical records?

A. Again, not aware given I had not seen this document.

Q. So, when you -- this document reflects that the Board of Medicine recognized that doctors could make a legitimate decision to prescribe opioids even in large doses for chronic pain, correct?

A. I think that's over-attributing a memo in my mind.

Q. That's what it says.

A. It's not a guidance. So, a physician would not interpret it as such. There are no references. It's not direct guidance. It's a letter stating do your job and we're going to back off. And that's basically what I would pull from that.

Q. And the Board here referred in particular to the prescribing of opioids for chronic non-malignant pain even in large doses as something that would not lead to disciplinary action if adequately documented. That's what the Board said, correct?

A. When all other measures fail, as stated in the first paragraph. I just think it's important for context that it wasn't stated in isolation that feel free to write whatever you want. They were pretty specific on the documentation on

the back of the page. The amount of documentation required for this is almost an impossibility, quite honestly, from a medical standpoint but, you know, when they put that there plus, you know --

Q. Dr. Waller, I asked you a very specific question. You just referred back to when all other measures fail. That's referring to the use of opioids in circumstances of suffering in the terminally ill when all other measures fail, correct?

A. It was -- so, if they're stating -- if they're stating that when all other measures fail, then you can use opioids in someone who is dying, my assumption is that they would also attribute that same statement to someone who is not dying from an illness of the pain that they have.

Q. That's not what it says, correct?

A. As a physician, I'm interpreting it differently than a lawyer.

Q. Well, I -- let's focus on the language then, Dr. Waller. The language of the second sentence in the first paragraph says, "There's a general consensus that opioids have a place in relieving intractable pain and suffering in the terminally ill when other measures fail regardless of diagnosis." Do you see that?

A. I see that.

Q. So, that's stating a general consensus, correct?

A. I would agree.

Q. Then the next sentence discusses the problem of treatment of chronic non-malignant pain in the non-terminal patient. That's what this policy statement is about, correct?

A. Well, that's the totality of the policy statement, but the little -- the individual pieces speak to them -- by themselves.

Q. Right. And, at this time, the Board recognized that one circumstance that would not lead to disciplinary action would be the use of opioids in large doses for chronic non-malignant pain, correct?

A. If 1 through 11 were also taken care of on the second part of the page. It's not just we can write it. All of these other pieces from my reading of this had to have taken place.

Q. A doctor needed to document and carefully consider this individual's circumstances of the patient before doing that, correct?

A. And a working diagnosis and a treatment plan that may involve a formal pain rehabilitation program, the use of behavioral strategies, the use of non-invasive techniques, or the use of medications, depending on the physical and psychosocial impairment. I mean, each of the --

COURT REPORTER: Can you slow down for me, please?

THE WITNESS: I'm sorry.

A working diagnosis and a treatment plan that may involve a formal pain rehabilitation program, the use of behavioral strategies, the use of non-invasive techniques, or the use of -- or the use of medications, depending on the physical and psychosocial impairment related to the pain.

Q. And if those --

A. And that's one of the 11. I mean, it's --

Q. Sorry. And if those factors were met, then a doctor could, in his or her judgment, prescribe large doses of opioids for the treatment of chronic non-malignant pain?

A. They're not stating -- what they're -- my interpretation of the document on first reading today is that what they are stating is that they are trying their best to not get in the way of a doctor making a decision and they're basically stating that this is an area that we don't have guidelines. And I'm not aware of guidelines for chronic non-malignant pain that actually did exist in 1997, if they did, not saying that I would because, again, I wasn't practicing medicine.

But reading this as a physician who practices medicine, who is managed and licensed by a State Board, if I was to receive this, I would state that what they are saying is that if you are a person who has to treat patients with severe pain that meet criteria, as I stated, even for

palliative care, which is different than what they had stated, which is more Hospice Care, how it would be categorized, then those patients may really need -- may need this.

It wasn't in my reading of this an open menu of everybody who has chronic pain should get large amounts of opioids without us coming and worrying about it.

Q. I'm going to put it, though, the other way, Dr. Waller. The Board of Medicine at this time is leaving it to the individual doctor to make his or her judgment based on clinical factors and documentation as to what level of chronic -- of opioids would be appropriate for the treatment of chronic non-malignant pain, correct?

A. Well, it was more than just documentation. There were actions that needed to take place.

Q. And if those -- if those took place, the Board recognized that doctors could use even large doses of opioids to treat chronic pain?

A. It said that they would not enforce -- they wouldn't take it upon themselves to enforce that action, is how I read that sentence, is that they wouldn't pick that out as something they would then enforce. It doesn't mean the DEA wouldn't, or the this, or the that, or the Medical Staff Chief of Pain Medicine wouldn't because, in that position, I was called many times to evaluate those things and we would

take notice.

Q. Okay. Let me show you another document.

MR. HESTER: May I approach, Your Honor?

THE COURT: You don't have to ask me every time. Once is good enough.

MR. HESTER: All right. I try to be friendly.

BY MR. HESTER:

Q. Dr. Waller, I've handed you a document. It's McKesson Exhibit 1218. It's headed "West Virginia Board of Medicine Quarterly Newsletter" from 2005. Have you seen this document before, Dr. Waller?

A. No, sir, not that I recall.

Q. Were you aware that the Board of Medicine in 2005 had issued another policy statement for the use of controlled substances for the treatment of pain?

A. I was not aware of this document.

Q. Is this the kind of document that you're generally aware of that State Medical Boards issue from time to time as a way to educate doctors in their state about developments in the practice of medicine?

A. In West Virginia, it seems this is the pathway that they use.

Q. And let me ask you to look at the first page and the notice, which is right up at the top, and you can see that it states here that the West Virginia Board of Medicine

adopted this policy at its meeting in January, 2005. Do you see that?

A. I do.

Q. And then, a few sentences further down, it says, "The following policy overrides all statements and policies relating to controlled substances for the treatment of pain previously adopted by the Board with one exception relating to end of life treatment." Do you see that?

A. I do.

Q. And were you aware that there was this decision made by the Board of Medicine around this time to issue a policy statement on the use of controlled substances for treating pain in West Virginia?

A. No, sir, I was not.

MR. HESTER: Your Honor, I would move McKesson Exhibit 1218 into evidence.

THE COURT: Mr. Farrell?

MR. FARRELL: Generally, as a plaintiffs' lawyer, Judge, I'm in favor of liberal admission of documents into the record. As long as we're afforded the same privilege, I have no objection.

MR. HESTER: I can't make any commitments on that, Your Honor. We're moving on this particular document.

THE COURT: Well, based on this witness's testimony, I don't think I can let it in if you object, Mr.

Farrell. Do you object?

MR. FARRELL: I do not object, Your Honor.

THE COURT: All right. It's admitted, there being no objection from any of the other parties.

MCKESSON DEFENSE EXHIBIT 1218 ADMITTED

BY MR. HESTER:

Q. Dr. Waller, let me point you to the second paragraph of this document on the first page and if you go to the sentence that begins accordingly, where it says, "Accordingly, this policy has been developed to clarify Board's position on pain control", do you see that?

A. I do see that.

Q. And do you have an understanding as you look at this document that it is a policy that was meant to clarify the Board of Medicine's position on using controlled substances in West Virginia to treat pain?

A. With the second part of the sentence, it seems to talk about that, but without fully kind of reading it and absorbing it, I'm not going to know what pain they're talking about because all it says is "position on pain control", which is overtly vague.

Q. Let me ask you to look at the second page, please. Do you see right at the first sentence at the top of the second page, it says, "The Board recognizes that controlled substances, including opioid analgesics, may be essential in

the treatment of acute pain due to trauma or surgery and chronic pain, whether due to cancer or non-cancer origins"? Do you see that?

A. I do.

Q. And were you aware that this was the policy as stated by the West Virginia Board of Medicine for the treatment of pain in West Virginia?

A. I was not.

Q. Were you aware there was a Congressional hearing in 2001 on the abuse of OxyContin?

A. Not that I recall, no.

Q. Something we heard about yesterday in openings. You -- you weren't aware of this?

A. I was not.

Q. So -- so, I take it you don't know whether this policy statement was issued after those Congressional hearings since you're not aware of whether there were such Congressional hearings?

A. Well, you stated that the Congressional hearings were in 2001 and the policy statement is 2005, so my assumption would be this was after that, but --

Q. Four years later, correct?

A. Based on the math.

Q. If I'm right on my 2001 date?

A. If you -- if -- I will take your word for the dates

given.

Q. Okay. Let me ask you to look at another document, please. Dr. Waller, I've handed you Defendant's Exhibit 2796, another quarterly newsletter issued by the West Virginia Board of Medicine, this one dated in 2009. Have you seen this document before?

A. I have not. You know, I wasn't asked to prepare statements on this, so I think this is going to be a common theme. My specific report was designed for me to answer basic questions about the proper use of pain, but not to really evaluate specific things. I'm happy to look at each of these. I just -- I think my answers are going to be consistently I don't know.

Q. You did talk about the use of opioids for the treatment of pain, correct?

A. And I'm happy to answer and can answer all questions related to my opinions on that.

Q. And I really just had one question for you on this, Dr. Waller, which I think is easy enough to cover. If you go to Page 6 of the document and you should look at these little numbers to the bottom left corner.

A. Okay.

Q. And this, this refers to the Board of Medicine in the Spring of 2008 distributing a book to every licensed physician and physician's assistant in West Virginia. Do

you see that?
A. I do.
Q. And the book that they're referring to there, if you look at the final sentence of the paragraph, it's the book written by pain expert Scott Fishman, MD. Do you see that?
A. I see that.
Q. And earlier today, I believe you had testified that this book written by Dr. Fishman was also circulated to doctors in Michigan?
A. That is correct.
Q. And it states here that the book was distributed through Medical Boards in 12 states. Do you see that?
A. I do see that.
Q. And were you aware that that happened, that the Fishman book was distributed to Medical Boards -- through Medical Boards in 12 states to doctors in those states?
A. I'd have to say, at that point, I was aware that it showed up on my desk, but as a brand new doctor that year, I was not aware of where it came from.
Q. And were you aware that the Fishman book was distributed to every doctor and every doctor's assistant or physician's assistant in West Virginia in 2008?
A. I was not aware of that.
Q. I believe you said you read the book by Dr. Fishman?
A. Many years ago now, yes.

Q. Let me show you the book.

A. Thank you.

Q. Dr. Waller, I've handed you a document marked as McKesson Exhibit 2111. Is this the book by Scott Fishman, MD that you referred to earlier in your testimony?

A. Well, seeing it in its Xeroxed form, it appears to be so.

Q. I should clarify. It is a Xerox of the book. We -- we are undertaking to get enough copies for everybody to have.

A. Oh, please don't.

Q. But I don't have them quite yet in the published form, but this is a photocopy of the book; is that your understanding?

A. It is my understanding.

Q. And let me -- and we can look at the title of the book if we look at Page 3, "Responsible Opioid Prescribing, A Physician's Guide. Scott M. Fishman, MD." That's the title and that's the author of the book you recall?

A. That's correct.

Q. Let me ask you to look at Page 137 of the book and for this purpose, you should be just looking at the numbers, the page numbers of the book itself. And this -- this page is where it describes Dr. Fishman. Were you aware Dr. Fishman had previously been the Medical Director of the Massachusetts General Hospital Pain Center at Harvard

Medical School? Did you know that?

A. I did.

Q. And the Massachusetts General Hospital is one of the most highly regarded hospitals in the world; is that right?

A. For certain specialties, yes.

Q. And the Harvard Medical School is a highly regarded medical school?

A. That is correct.

Q. And this is the book that was distributed to every licensed physician and physician assistant in West Virginia; is that correct?

A. I'd have to -- my assumption is that if you say that this was the one it was regarded to in here, I'll take your word for it.

Q. And this is the book that was distributed to you in Michigan?

A. As best I can remember. Again, it's been a number of years.

Q. And your understanding is that the Board of Medicine in Michigan distributed the book to every doctor in Michigan?

A. I'm not sure if it was every doctor or certain specialties of physicians.

MR. HESTER: I would move that McKesson Exhibit 2111 be admitted into evidence, Your Honor.

THE COURT: Any objection?

MR. FARRELL: I'm hesitant to say no, Judge, but my next witness wrote a bunch of books and I'll probably proffer them, too. So, no objection.

THE COURT: Is there any objection from anybody else?

Okay, it's admitted.

MCKESSON DEFENSE EXHIBIT 2111 ADMITTED

BY MR. HESTER:

Q. Let me ask you to look at Page 105 of the book. I want to point you in particular, Dr. Waller, to the last paragraph. Were you aware Dr. Fishman in this book said that there is, quote, "no debate among public health experts about the undertreatment of pain, which has been recognized as a public health crisis for decades?" Were you aware of that?

A. I was both aware of it and agree with it.

Q. You agree with that?

A. That the undertreatment of pain is an issue still in the United States.

Q. And let me ask you now to turn to Page 8 of the document, the book, and I wanted to point you to the paragraph under the heading of "A Countervailing Need", the second paragraph that begins "significant effort". Do you see that paragraph?

And here he states some propositions. He states them

as general principles that are widely accepted. Do you see that?

A. I see that.

Q. And the first such principle he states is, "Pain management is integral to good medical practice for all patients." Do you see that?

A. I do see that.

Q. Do you agree with that?

A. Yes.

Q. Next proposition, he states, "Opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic pain of both cancer and non-cancer origins." Do you see that?

A. I see that.

Q. And were you aware that Dr. Fishman's book had stated this proposition in 2008?

A. I was aware of that.

Q. Let me ask you to look over to the next page, Page 9. Do you see the statement at the very top of the page? "Patient should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient." Do you see that?

A. I do see that.

Q. And were you aware that Dr. Fishman's book stated this?

A. At the time of reading, yes.

Q. All right. Let me show you another document. Dr. Waller, I've handed you what's been marked as Defendant's Exhibit 1935 and, if you look at the second page, you can see it's another document from the State of West Virginia Board of Medicine. Do you see that?

A. I do.

Q. And you see on the second page, this is a policy on the use of opioid analgesics in the treatment of chronic pain, correct?

A. I do.

Q. And it's issued in September of 2013, correct?

A. It is.

Q. And it's another example of the kind of policy statement issued by the Board of Medicine to apprise doctors in West Virginia on standards of care for medicine in West Virginia?

A. It appears to be.

MR. HESTER: Your Honor, I would move Defendant's Exhibit 1935 into evidence.

THE COURT: Any objection to this one, Mr. Farrell, or by anybody else?

MR. FARRELL: Well, I would like him to do a little bit more than read the document and lay a little better foundation, Judge.

MR. HESTER: Well, I --

BY MR. HESTER:

Q. Dr. Waller, you're aware generally that guidelines like this are issued by Boards of Medicine from time to time to apprise doctors of standards of care?

A. This is not a guideline. A policy statement. Those are very different from a medical standpoint.

Q. Okay. You're aware that policy statements are issued from time to time by Boards of Medicine to apprise doctors of standards of care?

A. Yes.

Q. And is this an example of such a policy statement?

A. It appears to be.

Q. And have you seen this document before?

A. I have not.

Q. Excuse me?

A. I have not.

Q. Were you aware that this -- there was a policy issued by the West Virginia Board of Medicine in 2013 relating to the use of opioid analgesics in the treatment of chronic pain?

A. I was not.

MR. HESTER: Your Honor, I would renew my motion to have this admitted.

MR. FARRELL: No objection.

THE COURT: It's admitted.

MCKESSON DEFENSE EXHIBIT 1935 ADMITTED

BY MR. HESTER:

Q. And we spoke before that this policy was adopted in September, 2013; is that right?

A. It appears September 9th, 2013, specifically.

Q. And this was at a time when there was concern in the country around levels of prescribing of opioids?

A. Yes.

Q. And if you go to Page 3 of this document, let me point you to the third paragraph. It's numbered these -- these little numbered pages at the bottom here, Dr. Waller, so it's the third paragraph I wanted to point you to. "The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes." Do you see that?

A. I do.

Q. And were you aware that the Board of Medicine had taken that position as of 2013, that opioid analgesics are useful and can be essential in treating both acute and chronic pain?

A. I was not.

Q. Dr. Waller, do you happen to have your expert report handy? Do you have it there?

A. Not in front of me, no, I do not.

MR. HESTER: Let's see. Chris, can you pull up Dr. Waller's expert report?

BY MR. HESTER:

Q. I wanted to point you, Dr. Waller, to Page 28 of the report and maybe I should begin just by setting the foundation here.

MR. HESTER: Let's go back, Chris, to the first page.

BY MR. HESTER:

Q. This is the expert report -- cover of the expert report that you submitted in this litigation; is that correct, Dr. Waller? We can flip through it if you want.

A. No, that is the -- that is the cover page.

Q. So, let me take you to Page 28 of the document and I wanted to point you to Footnote 88. Now, let me hand it up to you, Dr. Waller.

A. Thank you.

Q. So, Dr. Waller, I was reading footnotes and I noticed Footnote 88 in your report at Page 28, so I wanted to go to Footnote 88. At Footnote 88, you cite an article by Compton and Jones, "Epidemiology of the U. S. Opioid Crisis, the Importance of the Vector". Do you see that?

A. I do.

Q. All right. Let me now show you that Compton article

and I want to talk to you about it.

A. Thank you.

Q. So, Dr. Waller, I've handed you what was marked as McKesson Exhibit 2079. Is this the paper, the Compton paper, that you relied on in your report and that you cited at Footnote 88?

A. Yes, it is.

Q. And you reviewed this paper in connection with preparing your expert report, correct?

A. I did.

Q. And you considered it to be a reliable source, correct?

A. For the specific purpose used in the paper, yes.

MR. HESTER: So, Your Honor, I move that McKesson 2079 be admitted into evidence.

MR. FARRELL: Judge, no objection, as long as we can attach behind it under the Rule of Completeness the actual report.

MR. HESTER: I don't agree with that, Your Honor. I wasn't moving that.

THE COURT: Yes. The Rule of Completeness would -- would allow you to introduce additional parts of this document if Mr. Hester offered only part of it. He used the report to lead into questioning about this. I don't think the Rule of Completeness applies here, Mr. Farrell.

MR. FARRELL: Would there be some other rule that

-- since --

THE COURT: You're the lawyer, Mr. Farrell. You're supposed to tell me.

MR. FARRELL: Well, it seems as if Mr. Hester is putting in a whole bunch of these documents and forgot one.

THE COURT: Well, I'm going to admit it.

MCKESSON EXHIBIT 2079 ADMITTED

BY MR. HESTER:

Q. So, Dr. Waller, let's look at Exhibit 2079, McKesson Exhibit 2079. The author of this paper is Dr. Wilson Compton, correct?

A. Correct.

Q. And he's the Deputy Director of the National Institute on Drug Abuse, correct?

A. Correct.

Q. Are you familiar with the National Institute on Drug Abuse?

A. Very familiar, yes.

Q. And it's referred to as NIDA?

A. NIDA.

Q. NIDA?

A. Yeah.

Q. There you go. And are you aware that NIDA's mission relates to the causes and consequences of drug use and addiction, that's their mission?

A. It is, yes. Amongst other things, but yes.

Q. So, let me ask you to go to Page 5 of the document, please. So, for this purpose, Dr. Waller, follow along with these numbers at the left bottom.

A. Okay.

MR. FARRELL: I'm sorry, counsel.

MR. HESTER: Sorry. It's number 5.

BY MR. HESTER:

Q. Let me point you, Dr. Waller, to the end of the first paragraph under the heading for prescription opioids and there's a statement at the very end of this paragraph that says -- Dr. Compton states, "It was, and is, through pain suffering and the shifting philosophies of pain treatment that today's opioid crises first took root." Do you see that?

A. I do see that.

Q. That's a true statement, correct?

A. As they saw it.

Q. I'm sorry?

A. As they -- as they saw the root. As an epidemiologist would look at the root. Because Dr. Compton, I mean, he's an epidemiologist, so his viewpoint of roots and those things would be purely based on numbers and not necessarily interaction. And so --

Q. Epidemiologists study the causes of disease?

A. Based on the data in which informs their decisions. So, there's a distinct difference between a number and a person.

Q. But your point is this -- you would see this as a true statement as a matter of epidemiology?

A. Yeah. As a matter of epidemiology, yes.

Q. So then, in the next paragraph, in the middle, there's a sentence that says, "Beginning in the 1980s, however, there were calls from some physicians and patient advocacy groups that not enough was being done to treat pain, both in cancer and palliative care patients, and even more generally." Do you see that?

A. I do.

Q. And that is a true statement, correct?

A. Both in the -- both in the sense of an epidemiologist and a physician.

Q. Then let me turn you over to Page 6, please, the next page of the document, the top of the first paragraph there on the left-hand column. "Pain advocacy organizations and some in the medical community began to seek state based regulatory changes to reverse the perceived underuse of opioids to address chronic non-cancer pain." Do you see that?

A. I do.

Q. And that's a correct statement?

A. True. Correct as based on the reference. And I haven't read that specific reference, so that's their interpretation of the reference, yes.

Q. And at the bottom of that same paragraph, there's a statement by Dr. Compton that "pharmaceutical companies were developing a new generation of extended-release opioid analgesics that contained more opioid per pill, but were promised to be less addicting, including Purdue Pharma's OxyContin." Do you see that?

A. I do.

Q. That's a true statement, correct?

A. Factually correct, yes.

Q. Okay. Let me point you to the second paragraph in the second column -- or the right-hand column. Sorry. About midway through, there's a statement that it became common for patients to go home from emergency rooms, hospitals and dental offices with prescriptions for enough opioids to last several weeks to a month to treat their acute pain, yet often needing only a few pills before their pain could be managed with over-the-counter medications. Do you see that?

A. I do.

Q. And that's a true statement, correct?

A. Again, per their interpretation of the reference, but as a direct matter, that was not the case from the emergency medicine field as I had interpreted it during my time

practicing emergency medicine.

Q. Do you have any reason to doubt Dr. Compton's conclusions as an epidemiologist here?

A. His conclusions on the other reference but, again, you know, it becomes a domino of what that reference looks like and what it stated. So, I can't state with certainty how his interpretation took place from a one-sentence statement from an entire paper. That's a lot to consolidate.

Q. Let me ask you to look at the next sentence where he states -- where Dr. Compton states, "As a result of these shifts in practice, the supply of prescription opioids increased four-fold between 1999 and 2010." Do you see that?

A. I do.

Q. "And unused pills became increasingly available for diversion and misuse." Do you see that?

A. I do.

Q. Is that a true statement?

A. Well, "the unused pills became increasingly available", yes, I think that's a -- that's a lot of supposition in the other -- there's a lot of assumption based on those last two words.

Q. Let me point you to the last sentence of the paragraph where Dr. Compton states in the last clause, "More than half of people who misuse prescription opioids report obtaining

them from family or friends who have prescriptions." Do you see that?

A. I do.

Q. That's a true statement, correct?

A. At the time from those data.

Q. So now, let's talk more about illicit drugs, such as heroin and Fentanyl. On the first page, let me take you all the way back to the first page of the article in the left-hand column, bottom of the page. Dr. Compton states that the, quote, "Opioid crisis in the United States is really two sets of intertwined issues: Misuse of and addiction to prescription opioid analgesics, which predominated in the first decade of the crisis, and, more recently, use of and addiction to illicit opioids." Do you see that?

A. I do.

Q. That is a true statement, correct?

A. I'm going to re-read it, if it's okay, just to make sure.

Q. Sure.

A. I think he left one out, but --

Q. Did I leave out a word or --

A. He left out a cause, but -- he said two sets of intertwined issues and I'd say it was more of a three-set braided issue, but --

Q. So, do you agree with the statement that Dr. Compton sets out here?

A. I think it's incomplete.

Q. Let me ask you about the next sentence. "Within the rubric of illicit opioid use, a further distinction can be drawn between the resurgent use of heroin and the problem of both deliberate and unintentional use of even more potent synthetic opioid drugs; namely, illicitly made Fentanyl and its analogs." Do you see that?

A. I do see that.

Q. And that's a true statement, correct?

A. From an epidemiologist's point of view, yes.

Q. Let me ask you to look at the second column on Page 1, the last sentence of that carryover paragraph. Dr. Compton states that, "Synthetic opioids are now almost twice as commonly involved in overdose deaths as prescription opioids or heroin." Do you see that?

A. I see that.

Q. That's a true statement, correct?

A. I would have to look at the reference for exactly what they were looking at, but I would take it as such.

Q. Let me ask you to turn to Page 5 of the document. At the very bottom of the left-hand column and carrying over to the top of the right-hand column, Dr. Compton states that, "There was a marked increase in overdose deaths from

illicitly made synthetic opioids generally related to Fentanyl beginning in 2013." Do you see that?

A. I do see that.

Q. And that's a true statement, correct?

A. It is a true statement.

Q. Let me ask you to look two sentences further down. Dr. Compton states that, "Fentanyl", he's talking here about illicit Fentanyl, right?

A. It doesn't specify. So Fentanyl, the minute that it leaves the hands of someone prescribed to becomes illicit, so it doesn't have to be imported or sold by a drug dealer. It can be Grandma's Fentanyl patch. So, I think it's just not specific enough.

Q. He starts that, the paragraph by referring to illicitly made synthetic opioids, correct?

A. Yes. So, if he's speaking about illicitly made and this is published in '19 and this data were gathered, I think, in 2013, most of that had a single specific source, but no.

Q. Do you see then in the sentence at the right-hand column it refers to the exceptional potency of Fentanyl estimated at approximately 50 times more potent than heroin? Do you see that?

A. I do.

Q. And that's a true statement, correct?

A. It's closer to 80 times. But close enough for an epidemiologist.

Q. So, illicitly made Fentanyl would be 80 times more times potent than heroin in your view?

A. It depends on how it's delivered, is the -- the key component to that, but --

Q. So, the way -- the way the illicitly manufactured Fentanyl is delivered into the body would affect the potency?

A. Not at the receptor. I mean, when I talked earlier today about there being affinity, how it binds and potency, how it turns, that would be the same, and that is about 80 times more, but the real danger with things like Fentanyl is how it's delivered.

Q. And when you say "how it is delivered", what are you referring to?

A. The route of administration.

Q. You mean whether it's being injected or snorted?

A. Or chewed.

Q. Or chewed?

A. Or a Fentanyl patch.

Q. And that can affect how potent the Fentanyl is?

A. It affects how rapidly the potency takes place and has its effect.

Q. Let me ask you to look at Page 7, please. Now, we're

under the heading for heroin in this paper, and I wanted to point you to the right-hand column.

A. I'm sorry. Was that Page --

Q. 7.

A. Sorry.

Q. A lot of numbers on here, so just focus on the ones on the bottom left. So, actually, I wanted to begin, I'm sorry, on the left-hand column. Dr. Compton states in the middle of that first paragraph, "The shift from southeast Asian heroin to, in particular, Mexican heroin facilitated the proliferation of heroin in communities across the United States through well established drug trafficking organizations and distribution channels that had long been routes for distribution of other illicit drugs, such as cannabis and cocaine." Do you see that?

A. I do.

Q. That's a true statement, correct?

A. That is.

Q. Let me point you to the right-hand column, top -- toward the top of the page. Dr. Compton states, quote, that "The influx of historically high-purity and low-cost heroin means that since 2010, drug abusers are increasingly likely to report that heroin was their first opioid misuse." Do you see that?

A. I do see that.

Q. That's a true statement, correct?
A. I think in its specificity.
Q. I'm sorry?
A. So, I think this is often mischaracterized in a sense that they say first opioid of, quote, "misuse", not use. And so, I just want to be clear that it's stating very specifically there are times and locations in which heroin, because of its ubiquitous availability and low price, becomes the first opioid that they misuse, not the first opioid that they use.
Q. So, your point is you can see misuse of prescription opioids or misuse of heroin and what Dr. Compton is reporting here is that there's a greater incidence of misuse of heroin as the first opioid of misuse?
A. Yes. Well, that's how it should be thought about in a sense of -- it's complex, the transition between prescription and heroin.
Q. But here, he's talking about what is the first opioid that's misused and we're seeing increasingly, since 2010, misuse of heroin as the first opioid misuse because of the historically low price and higher purity of heroin, correct?
A. Well, that and the definition of misuse as it changes with heroin as compared to prescription drugs. So, any use of heroin can be considered a misuse because it's a Schedule I and illegal, as compared to maybe taking two of your

three-in-a-day at night before you go to bed or maybe stack dosing the next day of your prescription. While you're still taking that many in a day and you're generally following that, that still wouldn't be considered misuse in the definition and the way that these authors evaluate it. So, just an important delineation.

Q. Let me ask you to look just further down in that same -- next paragraph. Dr. Compton states that, "As described by Journalist Sam Quinones in Dreamland, Mexican drug cartels were ready to satisfy the demand of the emerging market for illicit opioids by using new pizza delivery-like ways of marketing heroin to potential suburban buyers who otherwise might have been frightened to engage with the illicit drug trade." Do you see that?

A. I do.

Q. That's a true statement, correct?

A. Well, that's a statement from Sam's book and I would take it to be true.

Q. And the reference that Dr. Compton makes here to pizza delivery-type distribution of heroin, which is described in Dreamland, that refers to the fact that a heroin user could call a drug dealer who would make a delivery of the drugs, correct?

A. Correct.

Q. And the Dreamland book describes that phenomenon,

correct?

A. It does.

Q. I'm sorry?

A. It does.

Q. And that's one way that supply and availability of heroin expanded, right?

A. One of the ways.

Q. Let me ask you to look further down, the next paragraph. In this second sentence of the paragraph, Dr. Compton states, "Unlike in past decades, a higher purity means that" -- and he's referring there to higher purity of heroin, right?

A. Correct.

Q. "This higher purity means, among other things, that intoxication can be achieved with insufflation and smoking, thereby facilitating heroin initiation and use in a more acceptable way." Do you see that?

A. I do.

Q. That's a correct statement?

A. Incomplete, but correct.

Q. And insufflation, where he refers to insufflation, what is that?

A. Sniffing, snorting.

Q. Snorting of heroin?

A. Correct.

Q. So, the point being made here is that because the heroin was of a higher purity, it could be either smoked or snorted rather than injected, and that made it more likely that people would initiate than heroin, correct?

A. Well, and it was just -- yes, and it was compressed into pills, into tablets, and sold as such.

Q. Sold as heroin tablets?

A. Sold as opioid tablets. Sold as -- they say HOC. That's how they'd be labeled. You'd see H on one side, OC on the other.

Q. And that's an easier way for people to ingest heroin because it's being sold as a pill?

A. Well, when the purity became so high that, you know, they would have pills that looked just like a prescription pill. So, there were many times where people wouldn't know the difference what they were getting. So, they didn't even know that they were actually buying heroin many times.

Q. They might have thought they were getting a prescription opioid pill illicitly, but they were instead getting a heroin pill?

A. Correct.

Q. And when did that begin?

A. At about the same time we started seeing that, especially also with the addition of Fentanyl.

Q. And you started seeing that around 2010?

A. That's when I became really aware of it.

Q. And has it continued to grow since then as a phenomenon?

A. (Unintelligible).

COURT REPORTER: I'm sorry. What was your answer?

THE WITNESS: The answer is no. So sorry.

BY MR. HESTER:

Q. And so, sometimes -- sometimes, a prescription -- a counterfeit prescription opioid pill would be laced with Fentanyl and sometimes it might be a heroin pill?

A. Correct.

Q. And dealers were doing that because the prescription opioid pills were more expensive than heroin or Fentanyl?

A. Or they felt like they had someone who could get them the, quote, "drug they wanted" for a cheaper price and they would pawn it off as the same drug. So, they would say, "Do you have any oxy" and they would say "Yeah, I have that and it's half the price as this other guy," but it's actually not that. So, in their mind, they were replacing what they had been taking.

Q. So, they might be getting a pill either at a lower price or a drug dealer might be making a higher profit --

A. Right.

Q. -- because the drug dealer is selling it as a prescription opioid illicitly trafficked, but it's actually

a counterfeit with cheaper ingredients?

A. Correct.

Q. That actually gets me to a point I wanted to ask you about. Page 8, please. Dr. Waller, this may be just what you were talking about. At the bottom of the left-hand column where it says, "Dealers often adulterate heroin with synthetic opioids and adulterate other illicit drugs, including cocaine, methamphetamine and counterfeit prescription pills." Do you see that?

A. I do.

Q. And that's a true statement, correct?

A. That is.

Q. And at the bottom, at the very bottom of that first column, Dr. Compton states that, "This practice of lacing other prescription opioids with Fentanyl is extending the risk for opioid overdose beyond people who knowingly use opioids." Do you see that?

A. Yes.

Q. That's a true statement, correct?

A. It is.

Q. This is probably the same point, but let me just make sure I've got it nailed down with you. If you look at Page 5, in the paragraph right above Vector Factors, so we're on Page 5, right-hand column just above Vector Factors. There's a reference to a practice of pressing synthetic

opioids into counterfeit tablets that look like commonly misused prescription opioids. Do you see that?

A. I do.

Q. And that's what you were describing, that drug dealers were pressing Fentanyl into counterfeit prescription opioid tablets?

A. Amongst other things. Rarely pure. Well, never pure.

Q. Never pure Fentanyl?

A. No. The dose of a pure Fentanyl tablet the same size as a prescription tablet would be a hundred-fold what it takes to kill you, so it's cut.

Q. So, let's just make sure we've got that apples to apples. So, the potency of a Fentanyl pill the same size as a prescription opioid pill would be what? What's the difference in potency?

A. Well, potency, again, let me be clear. And I probably used that unclearly earlier, so I apologize. If we're talking about potency, there is a -- it is a specific biochemical nomenclature. It is something that describes -- the best way to think about it is if you have -- if the receptor is a dimmer switch and I say affinity, it's how tight that thing grabs the dimmer switch.

If I say potency, it's how much it turns up the dimmer switch. And so, a very highly potent drug will turn that dimmer switch all the way up and a lower potent drug will

turn it down. So, Fentanyl has a high potency as compared to other opioids. So, it will turn it up higher than say morphine, which would turn it up a lot, but not quite as much as Fentanyl.

And then there's also -- and that's what it does to the receptor. So, because of that, you have to change the dosing algorithm for it, meaning we use micrograms of Fentanyl as compared to milligrams of other substances.

Q. I just -- I wanted to do something really simple. This probably would not be done in the real world, but just to help us understand it, if you had a prescription opioid tablet and you put it next to a Fentanyl tablet of the same size, one of these counterfeit tablets pressed -- Fentanyl pressed into a counterfeit tablet, I take it that counterfeit tablet would kill somebody if it were the same size as the prescription opioid tablet?

A. Generally speaking, yes. A lot of factors, blah, blah, blah. But, generally speaking, it has a much higher potential for that.

Q. Because -- because it would -- it's such a large -- it would be so potent?

A. Yeah. It's a very high dose of a potent medication.

Q. So, another point you're making is that when you think about the addictive qualities or the harmful qualities of a drug, you also have to know about dose and duration,

correct?

A. Dose and duration. And a really interesting one is how fast it gets across the blood brain barrier to get to that reward center.

Q. Let me ask you to look at Page 8 again. In the middle of the second column, Dr. Compton says, "Given that how rapidly and with such devastating effects, synthetic opioids have overtaken heroin and prescription opioids, prescription-type opioids, it is imperative that the public health community remain vigilant to market development." Do you see that?

A. I do see that.

Q. And that's a true statement, correct?

A. I think it's a bit of a statement meaning the disconnect between epidemiology and clinical medicine, because people, generally speaking, don't have an addiction to or the drug that they seek out is not Fentanyl because Fentanyl lasts for 20 to 30 minutes. It's actually -- even though it's cheaper it's only 20 to 30 minutes and is very risky. And so, people who have already developed addiction still have an addiction to something like heroin that could have Fentanyl added. So, it's -- you're not going to see a string of, quote, Fentanyl Use Disorders in that sense.

Q. And another way to put that same point is people might end up ingesting Fentanyl and being harmed by it without

even knowing they were taking it, correct?
A. Correct. And I think it's been stated in a number of places probably more accurately as a Fentanyl poisoning epidemic because it's just added to so many things and it's acting more like a poison than it is a singular drug.
Q. And that poisoning wave has been going on for a number of years, correct?
A. In different geographies at different times and when it was switched over from China to Mexico.
Q. Let me ask you to look at Page 9 and here Dr. Compton states that, "The proliferation of illicitly-made synthetic opioids has disproportionately impacted states in the eastern part of the United States because of the differences in the underlying heroin markets." Do you see that?
A. I do.
Q. And that's a true statement, correct?
A. I don't see a reference with it, so it would be his interpretation based on the lower references, which I don't -- I don't -- I'd have to look at those.
Q. Let me -- let me point you to the next sentence then. Dr. Compton states that, "Since 2013, the majority of illicitly-made Fentanyl and Fentanyl analogs have been concentrated in states east of the Mississippi, where powder heroin, the predominate form of heroin, is more amenable to mixing with powder Fentanyl than is black tar heroin, which

is historically found in the western United States." Do you see that?

A. I do.

Q. That's a true statement, correct?

A. Chemically, very true, yeah.

Q. I'm sorry. You said "chemically, very true"?

A. Well, from a chemistry standpoint, the mixing of them is difficult between the difference between powdered and black tar heroin. Integrating the two, the substrate, is difficult.

Q. So, the point you're making is that the powder heroin, the white powder heroin, is easier to mix with Fentanyl, correct?

A. Correct, because they're both in the same state and dissolvable on the same substances.

Q. And the point Dr. Compton is making here is that we saw that predominantly in the eastern part of the United States, correct?

A. Yeah. More Eastern Seaboard, New York, New Jersey, Delaware. In fact, I would say New Jersey first and then --

Q. And into West Virginia, correct?

A. I would have to review the epidemiology, but I do know that they were affected. I just wouldn't be able to tell you to the specific amounts because I wasn't really asked to evaluate that detail.

MR. HESTER: Thank you, Dr. Waller. Those are all the questions I have.

THE WITNESS: Thank you, sir.

THE COURT: This looks like a good time to take a break. Let's be in recess for about ten minutes.

(Recess taken)

(Proceedings resumed at 3:42 p.m.)

THE COURT: Have you got anything, Mr. Nicholas?

MR. NICHOLAS: No questions from me, Your Honor. Thank you.

THE COURT: All right.

REDIRECT EXAMINATION

BY MR. FARRELL:

Q. Paul Farrell, Jr., for the plaintiffs.

Dr. Waller, good afternoon now.

A. Good afternoon.

Q. You were asked about MC-WV-02079, the Compton article. Would you please pull it out.

So I want to start with Page 6 -- I'm sorry -- Page 5. And I'm going to try to use some more of the court's technology.

This time I'm a little more familiar with this one, Judge.

The first thing is that what was read to you was this,

the first sentence. "It was, and is, through pain suffering and the shifting philosophies of pain treatment that today's opioid crisis first took root."

Do you remember that question being asked to you?

A. I do.

Q. So to be clear, in your experience, has there been a shift in the philosophy of prescribing opioids for pain in the United States?

A. I think it depends on which time frame we're talking about. So there --

Q. Hold on. Let me follow it up. The philosophy today, is it the same as it was in 2010?

A. No.

Q. The philosophy in 2010, was it the same as it was in 2000?

A. No.

Q. All right. The next sentence that was read to you was, "Beginning in the 1980s, however, there were calls from some physicians and patient advocacy groups that not enough was being done to treat pain, both in cancer and palliative care patients, and even more generally."

My first question is what is palliative care?

A. So palliative care is --

Q. End of life?

A. No, that's Hospice care. So palliative care would be

someone who has a painful illness that we have exhausted every other aspect of things we can do, all interventional pain techniques, surgeries, other medications, you know, and we really have no other thing that we can offer them in their treatment pathway. And, so, at this point, the risk benefit changes.

Q. All right. So, in general, what I'm asking you is this. Do you agree with the statement that beginning in the 1980s there was a shift in the philosophy of prescribing opioids?

A. Yes.

Q. All right. And it was at the call of some physicians and patient advocacy groups. You're aware of that?

A. As best as I could be.

Q. In general, you're aware of that in the realm of addiction medicine that there was a cycle that we went through where doctors were prescribing more pain -- or liberally prescribing more opioids?

A. Yes, for sure.

Q. My learned counsel, though, didn't read to you the next sentence. I don't know how well you can see it. But it says, "A now notorious one-paragraph letter in the New England Journal of Medicine in 1980 stated that among a large sample of hospitalized patients who had been given opioids, only four developed addiction," Footnote 50.

So my question to you is, is, are you familiar with what this now notorious one-paragraph letter is in the New England Journal of Medicine?

A. Yes, I'm familiar with this one.

Q. How are you familiar with it?

A. It was oft stated as the article that could be utilized to push opioids in the mid '90s as being low risk.

Q. I'm not going to have you guess. I'm going to actually put Footnote 50 up. Do you see Footnote 50?

A. I do.

Q. Will you read it into the record?

A. "Footnote 50, Porter, J. And H. Jick, 1980, addiction rare in patients treated with narcotics, New England Journal of Medicine, 302:123".

Q. Now, are you aware -- is this Porter and Jick article, is it widely cited in the medical literature?

A. Not anymore.

Q. Why not?

A. Because it's not research.

Q. Why not?

A. Because it's an opinion -- the methodological approach that they had taken had no power, no capability, no screening, no assessment for addiction in this population, and wouldn't be considered -- and even then, widely wasn't considered to change anybody's mind about practice. It was

one random person's opinion on their practice.

Q. Now, I promise I'm not getting into marketing and I'm going to keep this narrow. My question to you is: Why is this article infamous?

A. Well, it's infamous because from the information that I've been given -- and, again, I haven't done deep study on this, but this is definitely a large portion of the conversation is that it was utilized as the thing that people would point to to say that prescription drugs are not dangerous. See, we have this many thousands of people alive. It's a super low risk.

And there were people who would say, all right, there's this article. People would cite it. They would make these very clairvoyant statements and use that as a reference. And if you didn't follow up the reference and dig in, it created a lot of problems which is what happened.

Q. Are you familiar with Dr. Portenoy?

A. I am.

Q. And did he famously cite Porter and Jick to the medical community?

A. He did.

Q. And are you also familiar with who his corporate sponsor was?

A. Vaguely.

Q. Okay. Guess.

A. Pharma in general. I don't remember which one specifically.

Q. All right. So this Porter and Jick article, I'm going to pop over to -- do you remember the discussion that we had about this New England Journal of Medicine article? I think it's been admitted in the record as well.

A. Yes.

Q. Now, to be fair, New England Journal of Medicine, this is the preeminent medical journal in America. Agreed?

A. No.

Q. This is one of the preeminent journals in America. Agreed?

A. I would agree with that statement, yes.

Q. I mean, in all seriousness, New England Journal of Medicine, this is top shelf. This is the real deal.

A. It's supposed to be, but it has retractions as well.

Q. When people make mistakes, they, they admit them and sometimes they write letters --

A. Right.

Q. -- in the New England Journal of Medicine admitting them. Agreed?

A. Correct.

Q. So when we're looking at this particular one, and I forget the year that we said it was, --

A. '82, because I was 10, if I remember correctly.

Q. 1982. All right. You were shown the article and you weren't shown the references. So I'd like to take a minute and just peek at the references and ask you a couple of questions.

Number one, are there any references here in this article that you were taken through from 30 years ago that you recognized that we may have just recently discussed?

A. I kind of see reference number 8.

Q. And what would that be?

A. That would be Porter J., Jick H., addiction rare in patients.

Q. Reference Number 1, can you read what the title of reference Number 1 is?

A. "Planning for terminal care."

Q. Very good. Now, Number 2, read Number 2.

MR. HESTER: Your Honor, may I object? I believe the -- we did not admit this into evidence and the witness said he didn't have knowledge of it and I believe the Court has previously ruled that we can't simply read documents in through witnesses.

THE COURT: That's right, isn't it, Mr. Farrell?

MR. FARRELL: Well, I believe, Judge, that this was in particular presented to you. And I'm doing exactly -- I'm rehabilitating him on the exact same stuff he read.

THE COURT: Can you --

MR. FARRELL: Actually, I'm not even reading the article. What I'm doing is --

THE COURT: I can't remember, Mr. Hester. Did you refer to any specifics in this article up on the board or anything like that? I don't remember.

MR. HESTER: We did not admit it into evidence, Your Honor.

THE COURT: You used it to question him and you --

MR. HESTER: Yes, I mean, I should be clear, Your Honor.

THE COURT: You did play some of the --

MR. HESTER: I, I asked him about some of the quotations, yes, I did.

THE COURT: Did you put any of those up on the board for him to read?

MR. HESTER: I think, yes, I did, Your Honor.

THE COURT: I'm going to let you do it, Mr. Farrell.

MR. FARRELL: I won't belabor the point. In fact, I'll take it down and just read it.

BY MR. FARRELL:

Q. Were you aware that one of the references was on management of cancer pain with parenteral -- how do you say that?

A. Parenteral.

Q. Parenteral medication.

A. Well, I wasn't aware of the article, so I'll take your word for it.

Q. Were you asked about Footnote Number 5 which is an article that's entitled "The Distress of Dying"?

A. No.

Q. Were you asked about Footnote --

THE COURT: He hasn't answered the question.

MR. FARRELL: Oh, I thought he did.

THE WITNESS: I did. No, I was not aware. I was not asked about that.

BY MR. FARRELL:

Q. Were you asked about Footnote Number 6, Diseases of the Central Nervous System and Relief of Terminal Pain?

A. No, I was not.

Q. What about Footnote 7? Were you asked about the reference to medical management of chronic cancer pain?

A. No, I was not.

Q. What about Number 9, Drug Effects in Hospitalized Patients?

A. No, I was not.

Q. Getting back to the article that was admitted into the record -- this is, again, for the record MC-West Virginia-2079.

You were, you were shown and read into the record this

provision:

"On the basis of these studies, pain advocacy organizations and some of the medical community began to seek state-based regulatory changes to reverse the perceived underuse of opioids to address chronic cancer pain."

What I'd like to direct your attention to is to the bottom, and we're looking at Page 6.

And this is in the record now as a piece of evidence, so the Court can take its time to read it.

But I want you to look down and see that, that -- and read into the record starting with "the marketing of."

A. "The marketing of Oxycontin was particularly noteworthy. It included high levels of targeted outreach to primary care physicians, outreach at national meetings, incentivized sales, and even illegal sales practices, all of which fueled the multi-billion-dollar medication sales increase starting in the 1990s. These egregious practices found a particular niche in some rural areas where limited access to integrated pain treatment and high prevalence of pain conditions facilitated proliferation of prescription opioids and misuse. Areas of the United States, such as Appalachia, that historically did not have much illicit opioid trade became some of the epicenters of the prescription opioid crisis."

Q. Do you agree with the veracity and truthfulness of this

statement?

A. I do.

Q. All right. Now, I'm just going to do this. I'm going to slide this over here a little bit.

Now, this is another provision that was not referenced. It's why it's got the red underline in the same article in the record. Will you read that, please?

A. "The 1990s and 2000s also saw the development of rogue pain clinics (sometimes called pill mills) where opioids were prescribed and dispensed in large quantities but with few clinical indications."

Q. Do you agree with that statement?

A. I do.

Q. Let's just go to the very front page. Let's start with the very front page. Give the Judge some introduction to what the front page of this article is about. Can you read the first paragraph into the record?

A. Yes. "The U.S. opioid crisis is an extraordinary public health crisis that started at least two decades ago and has accelerated over the past decade. It is a significant driver of an unprecedented downturn in life expectancy among Americans. In 2017 alone, 47,600 people died from an overdose involving opioids in the United States. In addition, the economic cost of the crisis in the United States is estimated at more than $500 billion per

year."

Q. Do you agree with this statement?

A. I do.

Q. Now, you were read a couple of different portions as well. One of them was -- here we go. One of them was the Mexican heroin -- the Asian-Mexican heroin trafficking. Do you remember being read that provision?

A. Yes.

Q. All right. You weren't shown the portion directly above it, were you?

A. I was not asked to evaluate that portion.

Q. I'd like you to read the sentence before it.

A. "These millions of misusing or addicted persons, especially in the absence of adequate access to evidence-based addiction treatment, created a new market in the United States for heroin."

Q. Do you agree with this statement?

A. Definitely.

Q. Now, independent of this statement, do you agree that this is consistent with your testimony this morning about the chemical similarities of the molecule of heroin, oxycodone, and hydrocodone?

MR. HESTER: Object to leading.

THE COURT: Sustained.

BY MR. FARRELL:

Q. You were also asked to read this statement here. And this is about -- described by journalist Sam Quinones who wrote *Dreamland*. Do you remember being asked that?

A. I do.

Q. And you referenced him by his first name. Do you know Mr. Quinones?

A. We've met a few times, yes.

Q. Where have you met him?

A. At meetings giving talks, and he gave a talk at our national meeting for the American Society of Addiction Medicine. And then as I was giving educational talks, he would be at the same location. And I've had a couple of conversations with him.

Q. So he was listening to you or you were listening to him?

A. Both.

Q. Have you ever been on a panel with him?

A. Not on a panel, no.

Q. All right. So you were provided this -- have you read *Dreamland*?

A. Yes.

Q. I'm going to now show you the immediately preceding sentence to the one that you were shown. And I would -- if you'll recall, the *Dreamland* one was highlighted. And to be

fair to counsel, this sentence was also on the screen, but it wasn't highlighted and I'd like for you to read it.

A. "While the increased difficulty of obtaining diverted prescription opioids among people addicted to them appears to have contributed to expanded heroin use, market forces related to illicit drug trafficking have also played an enormous role."

Q. So in your mind as an expert in this case, do you have an opinion whether there is a direct relationship between prescription opioid abuse and heroin abuse?

A. There's a clear connection in my experience.

Q. How?

A. Well, there's two different angles from this.

The first one is hundreds, and now thousands, of patients that I've treated, I have done deep histories on each one of those people. And I've done that in multiple geographies, whether that be Michigan, New Jersey, other places where I do work, in California and other places.

And as I have spoken to them, the clear majority of those talk about the first prescription. And they talk about it with the same clarity as someone with an alcohol use disorder would talk about their first drink. And they would say, "The first time that I took this pill, I felt totally different."

That story is the common story. It is not a rare bird.

And as described in what happens as the dopamine goes down after they take it -- and, again, especially in people who are opioid naive or don't have other injuries or things like this, just taking an opioid does have those ramifications on the brain to varying degrees amongst individuals. But, at the same time, it is predictable in its nature.

And as that dopamine goes down and somebody says, "Okay, I think we're done with opioids," then all of a sudden, they don't have that opioid. That dopamine is low. And now, even though those were prescription and taken as prescribed, we now have someone that as we remove it, those behaviors of addiction become very apparent.

Q. Right. So let's stop right there and go to the next quote. This is from the same article that was entered into the record.

It says, "The relatively lower price of heroin (and now fentanyl, as described below) compared with prescription opioids may also have contributed to the transition from prescription opioids to heroin and other illicit opioids."

First question: Do you agree with this statement?

A. I do.

Q. Second question: Have you seen this or experienced this in your practice?

A. Not in my -- I have seen it happen. I haven't done it in my practice. I have, I have seen this occur in the

patient population that I treat ubiquitously. This is not an uncommon story.

Q. All right. In addition, there was read to you the talk about the geographic scope, right, the geographic scope. Do you remember talking about the geographic scope?

A. Yes.

Q. All right. See that word right there that I've got everything else covered up?

A. Yes.

Q. There were some statistics about West Virginia. So can you begin reading where I underlined?

A. "While there were 8.1 drug overdose fatalities per 100,000 persons in Nebraska in 2017, there were 46.3 per 100,000 persons in Ohio and 57.8 per 100,000 in West Virginia."

Q. Do you agree with this statement?

A. I, I do. In fact, this is one of the portions of the paper that I used for my reference.

Q. All right. So we'll go to Footnote 4. I see where it says Footnote 4 and get the attribution for the record.

Do you recognize what Footnote 4 is?

A. Yes.

Q. What is it?

A. It's the reference utilized to make those -- to do that statistical analysis.

Q. What is the reference?

A. This is the drug overdose deaths in the United States coming from the National Center for Healthcare Statistics.

Q. And is this a source of information that experts in your field reasonably rely upon when looking for data points?

A. Yes.

Q. Now, the other interesting thing that's in here is there's also -- and you were asked briefly about it -- public health responses. Are you familiar with public health responses to the opioid epidemic?

A. I am.

Q. How are you familiar with them?

A. I build them.

Q. And, so, one of the things it says is there's three aspects to it: Prevention, treatment, and harm reduction. Are you familiar with those three tenets?

A. I am.

Q. And then when you flip the page, it actually has in there five critical strategies and I'd like to talk about each of them with you briefly.

The first critical strategy is healthcare provider education, training, and guidance, including deployment of clinical tools such as PDMPs to monitor patient controlled substance prescriptions.

Do you see that first factor?

A. I do.

Q. Do you agree with that strategy?

A. I do.

Q. Is that strategy effective in combating the opioid epidemic?

A. It's been shown to be, yes.

Q. Would you endorse using one?

A. I would.

Q. Let's go to Number 2: Primary prevention of substance use, including opioid misuses. Do you agree that's a critical strategy for harm reduction?

A. It's a critical strategy for stopping the -- even the potential because primary prevention, just so it's clear to everybody, means never getting the pill.

Q. Why is that important?

A. Because the pill exposure is the key to, you know, all of this.

Q. Why?

A. Well, you can have all the genetic issues or health issues or trauma, you know, that you can find. But if the drug never comes into your body, you don't ever have to worry about those pieces. So without exposure, you don't end up with addiction to that substance that you're exposed to.

Q. Number 3: Expansion of medication treatment for OUDs. Do you agree with Number 3?

A. Definitely.

Q. How strongly do you agree?

A. So strongly that I'm the editor-in-chief of the book that describes how to build it and deliver it.

Q. What's the name of that book?

A. The ASAM Criteria.

Q. Now, is this what they call MAT?

A. MAT is Medication Assisted Treatment and it is one, one piece of a much larger pie that includes behavioral therapeutics, other medical evaluations and treatment, the care management pieces, appropriate therapeutic housing if needed, all of the other family-based therapeutic models, the community-based structure model required to stabilize someone long-term for addiction, not unlike we do for somebody who's had a heart transplant or has severe diabetes. We have these interventions set up for those types of things.

Q. Dr. Waller, do you believe in practice Medication Assisted Therapy?

A. Yes.

Q. I would like for you to take a moment and tell the Court why you believe Medication Assisted --

MR. HESTER: I was waiting, Paul.

BY MR. FARRELL:

Q. -- why you agree with Number 3 of the critical strategies.

MR. HESTER: Your Honor, I object. This witness has not been designated to testify to abatement issues in this litigation and is going beyond the scope of his expert report.

THE COURT: What's your response to that, Mr. Farrell?

MR. FARRELL: Well, my response is that we spent a good hour on this article and I'm following up on it.

THE COURT: Well, I'll overrule the objection and let you do it for a little while.

MR. FARRELL: Thank you, Judge.

BY MR. FARRELL:

Q. So Number 3, expansion of medication treatment for OUDs. Do you support that?

A. The evidence and I support it.

Q. So please tell the Court why.

A. So we've utilized Medication Assisted Treatment for half a century at this point. We have identified the fact that starting back in the '70s, the utilization of methadone in that setting decreased the mortality rate significantly in that group.

But it did more than that. It actually decreased

recidivism. It decreased poverty rates. It decreased sexual assault. It decreased HIV. It decreased Hepatitis C. It decreased CPS involvement. And we don't have any other meds that actually do all those other positive things.

And then in the early 2000s when we got buprenorphine, which is also known as the brand name Suboxone, we found that the utilization of that was close to equivalent.

And what I mean by equivalent is that for those started on Medication Assisted Treatment in an appropriate way, we see a 70 percent and higher retention and treatment rate. And if they're retained in treatment at one year, their chances of maintaining what we call short-term or long-term remission in addiction -- so we speak of it that way now. So we would say that someone has an opioid use disorder in short-term remission or long-term remission, which means that all those behaviors that we use to describe it are gone.

And they're on a medication, but they have no behaviors associated with the treatment of this that comport with the diagnosis of addiction. And, therefore, they work and they take care of their kids and, you know, they build their social networks and they stabilize their communities.

So it's not a -- I mean, the evidence is so strong and it's been there for greater than half a century. And, I mean, there are hundreds, thousands of publications that

back this up as well as I've got to say the number of people I treat. It's really cool.

Q. All right. I'm going to shift your attention now to -- you were asked a couple of questions about the complaint filed by the plaintiffs in this case. It's pretty big. Have you read the entire complaint?

A. I have not.

Q. So you were shown a couple of provisions. Now, this book that got sent around by Dr. Fishman that you got -- I think you said you got it in Michigan.

A. Yes.

Q. You were shown specific provisions about this book and the complaint of Dr. Fishman. I'd like for you to read the first sentence.

A. "Dr. Scott Fishman is a physician whose ties to the opioid drug industry are legion. He has served as --"

Q. Hold on. Before we get there -- I'm not going to spend a whole lot of time because this is in the record as well.

Are you aware of Dr. Fishman's relationships with industry?

A. I am now. I was not at the time.

Q. From where?

A. Hearsay and conversations and --

Q. We don't want to get in there. In general, in general, do you have any knowledge from the literature within your

field as to where Dr. Fishman stands today with regard to his positions?

A. Not particularly.

Q. I'm also -- remember that thing about writing letters and redactions. I'm going to highlight this other sentence in the complaint that wasn't read to you and ask you to read that into the record.

A. "He has himself acknowledged his failure to disclose all potential conflicts of interest in a letter to the Journal of the American Medical Association titled 'Incomplete Financial Disclosures' in a letter on reducing opioid abuse and diversion."

Q. So what is JAMA?

A. The Journal of the American Medical Association.

Q. Is it one of the preeminent publications in the United States medical industry?

A. It's considered as such, yes.

MR. HESTER: Your Honor, may I object? They're asking him to read the complaint.

MR. FARRELL: Judge, they did too. I'm just, for the rule of completeness, adding to the provisions they showed him.

MR. HESTER: It's an admission by the parties. It's an admission by the plaintiffs. They can't have their witnesses construing the complaint this way.

MR. FARRELL: Judge, to be clear, we're not running from our complaint. We're embracing it.

THE COURT: Well, what's the point? I mean, what are you trying to accomplish here?

MR. FARRELL: That's true. That's true. I've got one final question and that is the point I'm trying to make.

THE COURT: Okay. I'll overrule the objection and let you ask your one question.

MR. FARRELL: Thank you.

BY MR. FARRELL:

Q. Paragraph 616. It says, "In another guide by Dr. Fishman, he continues to downplay the risk of addiction. His quote: 'I believe clinicians must be very careful with the label 'addict.' I draw a distinction between a chemical coper and an addict. The guide also continues to present symptoms of addiction as symptoms of pseudo-addiction.'"

One question to you: Is this still the standard of care?

A. It's never been the standard of care.

Q. Now, one final area of inquiry. You were asked a lot of questions about doctors from all over writing, writing prescriptions. I've got a couple questions for you.

Are you aware of whether or not the West Virginia Board of Medicine has revoked any West Virginia medical licenses

of doctors for inappropriately prescribing opioids?

A. I'm not aware.

Q. All right. Are you aware of whether the U.S. Attorney for the Southern District of West Virginia has indicted, convicted, and sent West Virginia physicians to prison for inappropriately prescribing opioids?

A. I don't know any specifics, no.

MR. FARRELL: I don't have any further questions, Judge.

THE COURT: Do you want --

Ms. Wicht, do you want to go next?

MS. WICHT: Your Honor, I was going to have Mr. Hester go first and I would only follow up if there's something additional to that.

THE COURT: Okay.

RECROSS EXAMINATION

BY MR. HESTER:

Q. Dr. Waller, just a few brief questions.

You were asked some questions about how to treat substance abuse. And am I correct that there's nothing in your report that specifically addresses the abatement plans that have been presented in this case?

A. I believe in my report I did discuss the provision of use of Medication Assisted Treatment in general approaches to care. And that was: What are the standards for treating

opioid addiction and dependence on Page 52.

Q. That's all you did in your report?

A. It was sprinkled throughout in substance, but this is the only place where I directly specified the standard treatment for opioid use disorder.

Q. And you stated in your experience that you see 70 percent of patients in remission, short-term remission after one year; is that correct?

A. At the population level of people on the medication. So if you took the totality of the literature, the, the average outcome would show 70. We were at 84 percent in my clinic.

Q. So you -- in your work you've achieved an 84 percent remission rate after one year?

A. On average, yes.

Q. You were asked about the Porter and Jick letter. You knew about that letter. When did you learn about that letter?

A. About the same time that they had mentioned other things about the '90s and that. But it came into my lap more often as I became the chief of pain medicine when I was talking about -- when I was having to get physicians to try to decrease their prescribing habits in a hospital and they kept poking it in my face.

Q. Who are Porter and Jick?

A. I don't know them individually.

Q. You don't know who they are?

A. I believe they were surgeons, but I would be speaking out of just remembering.

Q. So those were opinions stated by doctors?

A. Correct.

Q. And, and they published their letter where?

A. In the New England Journal of Medicine.

Q. And as a way to influence the views of doctors? Is that your view?

A. I wouldn't be able to creep into their head to make that distinction.

Q. Let me show you --

Can we bring up Paragraph 394 of the complaint if possible?

Dr. Waller, I'm showing you Paragraph 394 of the plaintiffs' complaint in this litigation. Can you see that?

A. I can.

Q. And does this refer to Purdue relying on the Porter and Jick article as promotional material for their Oxycontin product?

A. Let me read it real quick.

(Pause)

It appears to be, yes.

Q. And was it your understanding that, that Purdue was the

one that relied on the Porter and Jick article to promote the use of opioids?

A. I learned that at a later date. Actually, it was probably within the last three to four years is when I really thought even about that type of the issue and that came up in other ones. I had originally seen it as other people had presented it to me as evidence of low rate.

Q. Other people meaning sales representatives?

A. Colleagues.

Q. And are you aware of any time when distributors have used the Porter and Jick letter to promote opioids?

A. Not in my scope of evaluation, no.

Q. Let me ask you to look at the Compton article again. You're going to learn to love this article.

A. I do like it.

Q. Let me point you to Page 6, please. And the paragraph that Mr. Farrell read to you, which is at the bottom of that left-hand column, it begins, "The marketing of Oxycontin was particularly noteworthy. It included high levels of targeted outreach to primary care physicians."

Do you see that?

A. I do.

Q. That was marketing activity being engaged in by Purdue; is that correct?

A. In -- I, I've heard that it was. It's just not a part

of my research.

Q. But your understanding is that this outreach to primary care physicians was being done by manufacturers; is that right?

A. Yes.

Q. Let me ask you to look at Page 7 of the Compton article, please. And under the heading for "heroin," Mr. Farrell referred you to the growing population of individuals who were either misusing or had become addicted to prescription opioids. Do you see that? It's right in the top under "heroin."

A. Yes.

Q. And there's a reference there to marketing of heroin. I'm going to be starting at the start of that paragraph.

"Marketing of heroin has also shifted with changes in both the supply countries (i.e. from Southeast Asia sources in past years to Central and South America as the predominant suppliers of the U.S. heroin market) and new sales techniques by drug dealers who took advantage of the growing population of individuals who were either misusing or had become addicted to prescription opioids."

Do you see that?

A. I do.

Q. Is that a correct statement?

A. I'm not terribly familiar with the marketing

techniques. I do have deeper knowledge in some aspects of the drug trade.

Q. But you are aware that there were new sales techniques by drug dealers taking advantage of those who had become addicted to prescription opioids?

A. Oh, absolutely.

Q. Let me ask you to look at Page 8, please, of the Compton article.

Mr. Farrell referred you to this right at the top of the left-hand column, referred to the point that, "The relatively lower price of heroin and now fentanyl as described below compared with prescription opioids may also have contributed to the transition from prescription opioids to heroin and other illicit opioids."

Do you see that?

A. I do.

Q. And Mr. Farrell asked you about that. Do you recall?

A. I do.

Q. Who sets the price of heroin?

A. The market.

Q. And that's drug dealers; correct?

A. I'm not fully aware of the internal workings of that world. But, generally speaking, it's, it's actually set regionally from above the actual street dealer level.

Q. But illegal drug dealers are the ones who are setting

the price of heroin; correct?

A. As far as I understand the drug trade, yes.

Q. And illegal drug dealers are also the ones who are altering and changing the purity levels of heroin; correct?

A. Actually, not the dealers in that sense.

Q. Cartels are the ones that are changing the purity levels of heroin?

A. Generally speaking, it's happening before it's shipped.

Q. And it's not being done by distributors of lawful prescription opioids; correct?

A. As far as I'm aware.

Q. Thank you, Dr. Waller. Those are all the questions I have.

RECROSS EXAMINATION

BY MS. WICHT:

Q. Good afternoon, Dr. Waller. These segments are getting shorter and shorter and I'll be very brief.

I am going to return for just one moment to the Compton article to a portion that --

A. It's been broken in.

Q. Exactly -- that Mr. Farrell showed you.

Is it possible to switch over to the ELMO? Okay.

Mr. Farrell asked you about five critical strategies in order to combat the opioid crisis --

A. Uh-huh.

Q. -- and had you walk through them. And I just have just a few follow-up questions on that.

Strategy Number 1 is healthcare provider education, training, and guidance including the deployment of clinical tools such as PDMPs.

And my question for you, sir, is deployment of that strategy wouldn't involve wholesale distributors in any way, would it, or their conduct?

A. I, I don't know all of the inter-connectivity it would have there if they would support that through grants or things like that. But -- so, you know, I don't know.

Q. A fair point. Would it, would it -- independent of them supporting it in some way through funding, are you aware would healthcare provider education and use of PDMPs require any change in distributor conduct as they go about their business that you're aware of?

A. I mean, I can think of a few places where it would be helpful if they leaned in. And that would be helping to utilize PDMP data to identify certain bridles of opioids in certain areas that are being overutilized and to re-evaluate how they deploy that; and then also making sure that what they have on the shelf comports with what is best practices.

Interestingly, what you carry also changes what can be ordered, you know, on back order. And that's -- so what's carried in a warehouse many times limits what a pharmacist

can order.

So they may go to order it and it's not there so they pick something equivalent. And having safer equivalents in that same space to be available as a lower price point as compared to other ones would be actually very helpful.

Q. Dr. Waller, isn't it correct that distributors legally do not have access to PDMPs?

A. Not in all states. There are a few states that those things can be aligned.

Q. Are you aware that other distributors have access to the PDMP in West Virginia?

A. I don't know the rules or regs specifically around the West Virginia PDMP.

Q. In fact, distributors -- so you're not aware that distributors do not have access to the PDMP in West Virginia?

A. No. Very few people have access to the, quote, PDMP. But the identified data geographically specifically from a research -- you don't need individual data. It's more aggregate. And I agree that that can only happen through a special contract mechanism in most states. There are a couple that allow for that interaction.

Q. And are you aware that that doesn't exist in West Virginia?

A. If you're stating it doesn't exist, I'll take your word

for it. I haven't looked into it specifically in West Virginia.

Q. Just a question to you, so that's fair enough. I'll take it the answer is you don't know.

Okay. The second critical strategy, primary prevention of substance use, including opioid misuse, and you testified that that was preventing the patient from getting the pill in the first place. Correct?

A. Primary prevention is the prevention of any contact with the initiative of a disease process.

Q. So is it your testimony as you sit here today that if a physician writes a prescription for an opioid medication, a distributor should refuse to stop that medication in the pharmacy? Is that your testimony?

A. No, not at all.

Q. So primary prevention of substance use, including opioid misuse, stems from the doctor's prescription in the first place; correct?

A. In one of the pieces. I mean, that's not the only place that people get access.

Q. Let's look at the third critical strategy, expansion of medication treatment for OUDs. Would distributors have any involvement in that other than the routine distribution of medication that would be used?

A. There have been some issues with distributors

specifically having access to it and being able to deliver it as needed in areas I know of.

But -- so other than making sure that access is granted and capability for availability of the right doses and types and that, so -- the point is that it would be great if the distributors were involved in all of these things and many of these things, you know, could have been really helped by distributors.

Q. Are you aware of any of the distributors who are here today, Cardinal Health, McKesson, AmerisourceBergen, refusing to distribute Medication Assisted Treatment for OUD?

A. I don't have knowledge of any specific instance.

Q. Okay. And let's look at critical strategy number 4, access to and use of naloxone. Let me ask you the same question I just asked. Are you aware of any of the distributors who are sitting here in this courtroom today, Cardinal Health, McKesson, AmerisourceBergen, refusing to distribute naloxone?

A. Not that I'm aware of.

Q. Item Number 5, implementation and scaling of comprehensive syringe services programs and other harm reduction programs.

Are those programs that distributors would have any involvement in other than routine distribution of necessary

supplies that were ordered by the participants?
A. I would say the distributors could fix that problem all by themselves if they wanted to. In your warehouses sits millions of clean syringes.
Q. Are you aware of any of the distributors who are sitting in this courtroom today refusing to distribute syringes to any customer who has ever ordered them?
A. I was speaking as an abatement process to help a community, not as an ROI.
Q. Not as a -- I'm sorry. What was the last word you said?
A. Return on investment, meaning syringes sit in warehouses, your warehouses.
Q. Until customers order them; correct?
A. Or until it's felt to be in the greater good to actually give away some of those so that we can decrease harm.
Q. So what you are suggesting is a voluntary contribution by distributors?
A. Wouldn't that have been great before we saw HIV explode in Indiana or Hepatitis C decimate entire portions of the country?
Q. Are you aware of whether any distributors, in fact, have undertaken such programs?
A. I am not.

Q. That's all I have. Thank you.

MR. FARRELL: No further questions.

THE COURT: Do you have anything else of Dr. Waller? May I excuse him?

MR. FARRELL: Yes, you may, Your Honor.

THE COURT: Dr. Waller, thank you for spending the day with us, sir. You've been very helpful to us and we appreciate it and you are free to go.

THE WITNESS: Thank you, Your Honor.

THE COURT: Thank you very much.

(Witness stood aside)

MR. FARRELL: I'm trying to read your facial expression.

THE COURT: Well, this is the first day of the evidence and I hate to establish a precedent of stopping early when it's convenient to do so, but you probably have another witness that's going to take some time.

MR. FARRELL: I do. And, in fact, I believe we could probably fill up 10 or 15 minutes. Mr. Ackerman has a proffer to make and there may be some evidence stuff we can talk about.

THE COURT: Okay. Let's do that and then we'll pull the plug.

MR. ACKERMAN: Good afternoon, Your Honor.

THE COURT: Good afternoon.

MR. ACKERMAN: David Ackerman for the plaintiffs.

THE COURT: Yes.

MR. ACKERMAN: Your Honor, at this time plaintiffs request that the Court take judicial notice of plaintiffs' Trial Exhibit 2270 which is a transcript of the testimony of the Acting Administrator of the DEA on March 20th, 2018, before the House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. And we offer this document into evidence pursuant to the public records exception to the hearsay rule.

THE COURT: Any objection to this?

MR. SCHMIDT: Yes, there will be, Your Honor. Let us pull up the exhibit if we can. This is the first time we're hearing that it was going to be moved in this way.

MR. FARRELL: Judge, if you prefer, we can do this tomorrow morning first thing if they want some time. I didn't realize --

THE COURT: Yeah. Are you surprised by this, Mr. Schmidt?

MR. SCHMIDT: Well, I think what happened is it was sent to us as an exhibit for Dr. Courtright last night. So if it's 2270, I now have it in my hand. It's an exhibit that says, "This is a preliminary, unedited transcript. The statements within may be inaccurate, incomplete, or misattributed to the speaker. A link to the official

transcript will be posted on the committee's website as soon as it becomes available."

We just didn't know -- that would be our first objection. We just didn't know this was going to be moved in in this manner.

MS. MCCLURE: Moreover, Your Honor, this exhibit is not on Dr. Courtright's -- Ms. McClure, sorry. Shannon McClure, AmerisourceBergen Drug Corporation.

It's not on Dr. Courtright's reliance list and we underscore the authenticity issues that are noted as plaintiffs' 2770. We were not aware that the plaintiffs intended to proffer this document at the start and is not in the course of Dr. Courtright's testimony.

There are other issues associated with the relevance, completeness, geographic scope, hearsay, et cetera. But the key here is that this document is not included in Dr. Courtright's reliance list. It's not referenced in his report. So I would request some understanding as to what your proffer is here.

MR. ACKERMAN: Mr. Farrell wants to speak and I always defer to him.

MR. FARRELL: Let me shortcut this, Judge. We will retake this up tomorrow morning. I think we've given them the wrong version. I don't want to belabor the point. Perhaps they can have some discussion.

This is not pursuant to Dr. Courtright's deposition. We're asking the Court to take judicial notice. We can address it first thing tomorrow morning.

MS. MCCLURE: We did not understand anything about this judicial notice plan. We simply received a document and understood it would either be related to Dr. Courtright or to Dr. Waller.

We're now understanding for the first time, I believe, that this is a document that you're intending to ask the Court to take judicial notice of.

THE COURT: Is this a transcript of testimony?

MR. ACKERMAN: It is, Your Honor.

THE COURT: Well, you're going to have to explain to me how it comes in under the public records exception --

MR. ACKERMAN: Yes, Your Honor.

THE COURT: -- because it seems to me it's a public record but that wouldn't make what's inside it admissible if it's testimony.

MR. ACKERMAN: Well, Your Honor, what we're requesting -- and, again, we can do this tomorrow or now if you'd like -- is that the Court take judicial notice of the hearing and accept the transcript as a, as a public record.

What is in the transcript, Your Honor, are the statements of the Acting Administrator of the DEA who is making statements setting out the office's activities and

reporting factual findings from a legally authorized investigation pursuant to Rules 803(8)(a)(1) and (a)(3).

I would further note, Your Honor, that in *SEC* vs. *Pentagon Capital Management* which is at 722 F.Supp. 2d 440, Southern District of New York in 2010, the Court similarly accepted testimony from the SEC. I believe it is the Director of the SEC's Division of Enforcement pursuant to the public records exception under the same rationale.

MS. MCCLURE: So, Your Honor, this is the first we're hearing of this. We would suggest taking Mr. Farrell up on his suggestion that we have the opportunity to meet and confer with the plaintiffs about this which we have heard this for the first time today.

THE COURT: I'm going to recess until tomorrow morning. And you know what my concern about it is and you were obviously surprised and need some time to consider it.

So I think it's appropriate to adjourn until 9:00 in the morning and we'll take this up first thing in the morning.

MS. MCCLURE: Thank you, Your Honor.

(Trial recessed at 4:37 p.m.)

CERTIFICATION:

I, Ayme A. Cochran, Official Court Reporter, and I, Lisa A. Cook, Official Court Reporter, certify that the foregoing is a correct transcript from the record of proceedings in the matter of The City of Huntington, et al., Plaintiffs vs. AmerisourceBergen Drug Corporation, et al., Defendants, Civil Action No. 3:17-cv-01362 and Civil Action No. 3:17-cv-01665, as reported on May 4, 2021.

S\Ayme A. Cochran
Reporter

s\Lisa A. Cook
Reporter

May 3, 2021
Date

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